

## DOCTOR OF CLINICAL PSYCHOLOGY (DCLINPSY)

### Doctorate in Clinical Psychology: Research Portfolio

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**Research Portfolio**

Volume 1 of 2

Submitted in part fulfilment of the requirements for the degree of Doctorate in Clinical Psychology

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May 2014

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## **Abstracts**

### **Main Research Paper**

**Objective:** Somatisation as a process suggests that mood changes are responded to physically rather than psychologically. This concept is linked to “medically unexplained symptoms”, including conditions such as chronic fatigue or fibromyalgia. Alexithymia, difficulty in identifying or expressing emotions, is the proposed causal mechanism. This study tested this proposal by measuring association between alexithymia and somatic symptoms and exploring whether experimentally induced mood changes are responded to by those with higher alexithymia scores with more physical than psychological sensations than those with lower alexithymia.

**Methods:** A median split of Toronto Alexithymia Scale scores was used to create two groups (higher and lower alexithymia) from a sample of 21 participants with a diagnosis of chronic fatigue syndrome and / or fibromyalgia. Participants rated mood and physical and psychological state at baseline and following sad and happy mood induction. Ratio scores of psychological over physical state ratings were calculated for each mood state. Measures of depression, anxiety, somatic complaints, acceptance, beliefs about emotions and health anxiety were also administered.

**Results:** No correlation was found between alexithymia and intensity of somatic or psychological symptoms. There was no significant difference in ratio scores by mood or between those with higher or lower alexithymia. The mood manipulation did lead to changes in psychological sensations and physical sensations.

**Conclusion:** The alexithymia hypothesis of medically unexplained symptoms was not supported in this study using a clinical sample. Further research should include a control group of people experiencing depression or anxiety without significant physical symptoms.

### **Service Improvement Project**

**Objectives:** This study aimed to explore perceived barriers and facilitators to engagement with early intervention for psychosis (EI) services and to investigate the perceived relevance to service users and staff of illness perceptions as a way of improving engagement.

**Design:** Qualitative study with semi-structured interviews.

**Methods:** EI staff (six participants), service users (four) and family members of service users (six) were recruited from an EI service in Gloucester. A brief interview schedule was used which asked

about barriers, facilitators to engagement, attitudes to illness perceptions as relevant to engagement and suggestions for interventions based on illness perceptions to improve engagement. Key points were transcribed. Data were analysed using Framework analysis.

Results: Barriers and facilitators to engagement were perceived at a range of levels, from wider social issues through health-care management and service design, to staff behaviours and service user perceptions. Illness perceptions were seen as relevant by all. A range of formats were seen as necessary to support engagement across different service users. Practical activities to show service users how EI can be useful and sharing service user experiences were seen as particularly helpful to support engagement.

Conclusions: Intervention focusing on assessing and adapting illness perceptions is relevant and potentially acceptable to service users, families of service users and staff. Suggested interventions now require further development and evaluation.

### Critical Literature Review

Post-traumatic stress disorder (PTSD) is an important issue in sub-Saharan African where violent conflict and natural disaster are experienced. The cognitive model of PTSD (Ehlers and Clark, 2000), has received substantial support. Its applicability to a sub-Saharan Africa context is unclear. Various interventions exist to target PTSD. Their use and cultural adaptations require synthesis. Cognitive-behavioural therapy (CBT) has been found effective for treating PTSD but its effectiveness in this context requires analysis. To address these three issues, Medline, PsycInfo, EMBASE and CINAHL were searched for sub-Saharan African nation names and trauma terms. Studies providing previously unreported data relating to the model were included. Controlled intervention studies were identified, from which CBT effect data were extracted. A narrative synthesis is provided, with meta-analysis for effectiveness of CBT. 18 studies addressed the model, providing support for it. Fourteen intervention studies were identified, revealing inclusion of participants without PTSD diagnosis. Cultural adaptations focused on content. Eight CBT studies were identified. Meta-analysis revealed "Narrative Exposure Therapy" (NET) as not effective, whilst standard CBT appears effective. However, standard CBT studies tended not to include an active control. Overall, the lack of focused model-related research and heterogeneity in intervention studies highlights the need for further high-quality research.

## **Word counts**

Critical literature review	- 6,936
Service improvement project	- 4,991
Main research paper	- 4,000
Executive summary	- 789
Connecting narrative	- 2,999

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Doctorate in Clinical Psychology, University of Bath

**Critical Literature Review: PTSD in sub-Saharan Africa: A Systematic Literature Review of Evidence for the Cognitive Model, Interventions Researched and Meta-analysis of Effectiveness of Cognitive Behavioural Therapy**

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### **Abstract**

Post-traumatic stress disorder (PTSD) is an important issue in sub-Saharan African where violent conflict and natural disaster are experienced. The cognitive model of PTSD (Ehlers and Clark, 2000), has received substantial support. Its applicability to a sub-Saharan Africa context is unclear. Various interventions exist to target PTSD. Their use and cultural adaptations require synthesis. Cognitive-behavioural therapy (CBT) has been found effective for treating PTSD but its effectiveness in this context requires analysis. To address these three issues, Medline, PsycInfo, EMBASE and CINAHL were searched for sub-Saharan African nation names and trauma terms. Studies providing previously unreported data relating to the model were included. Controlled intervention studies were identified, from which CBT effect data were extracted. A narrative synthesis is provided, with meta-analysis for effectiveness of CBT. 18 studies addressed the model, providing support for it. Fourteen intervention studies were identified, revealing inclusion of participants without PTSD diagnosis. Cultural adaptations focused on content. Eight CBT studies were identified. Meta-analysis revealed “Narrative Exposure Therapy” (NET) as not effective, whilst standard CBT appears effective. However, standard CBT studies tended not to include an active control. Overall, the lack of focused model-related research and heterogeneity in intervention studies highlights the need for further high-quality research.

## **Introduction**

### **Background and Rationale**

Sub-Saharan Africa (referring to the nations south of the Sahara desert) has experienced a disproportionate level of conflict with often brutal violence and rape used as a weapon (Collier & Hoeffler, 2002; Edwards, 2005a), in addition to violent crime and life-threatening accidents that occur globally. Post-traumatic stress disorder (PTSD) is a significant burden in the region. Prevalence is difficult to estimate. The World Health Organisation calculated disability adjusted life years for PTSD (healthy years of life lost owing to a particular condition) in 2004 of 355 for Africa (including northern African states), compared to 183 in the developed Americas (largely the United States) and 203 in high income Europe (WHO, 2008). This impact may be under-estimated in less developed regions due to practical challenges of collecting data. The majority of research into PTSD and its treatment has taken place in high income Europe and the United States, despite perhaps a greater impact of PTSD in areas such as sub-Saharan Africa and low income parts of Asia.

There are several psychological models of PTSD, leading to different treatment types. The cognitive model by Ehlers and Clark (2000) has led to the development of cognitive-behavioural therapy (CBT). CBT has a strong evidence base for PTSD (e.g. NICE, 2005). Limited evidence for the transportability of the Ehlers and Clark model has been summarised for Africa, with the effectiveness of interventions based on the model taken as support (Edwards, 2005b). An updated synthesis of research is needed to explore the extent to which elements of the model are supported in sub-Saharan Africa.

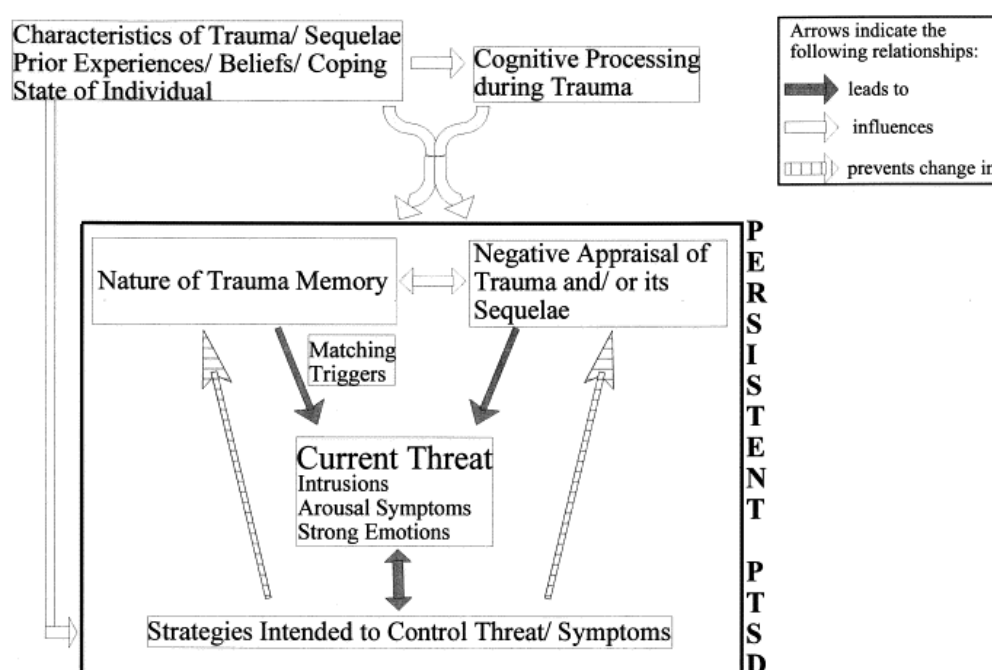
Mental health care remains poor across the region, presenting an humanitarian need and a barrier to realising Millennium Development Goals (Skeen, Lund, Kleintjes, Flisher, & Mhapp Research Programme Consortium, 2010). Interventions to provide treatment of PTSD amongst other mental health conditions are required. CBT for PTSD has been adapted for people from a variety of countries, including Cambodia, Uganda and Vietnam (Otto & Hinton, 2006; Sonderegger, Rombouts, Ocen, & McKeever, 2011). The interventions used and their adaptations in sub-Saharan Africa requires investigation to understand how to optimise interventions.

Cognitive behavioural interventions are increasingly popular globally, however their evidence base is mainly from “Western” samples in “Western” settings (Naeem, Phiri, Rathod, & Kingdom, 2010) with single trauma only, differing from the experiences of many refugees for example. It has been commented that “The evidence base for ‘in-country psychosocial interventions’ is significantly lacking when compared to the existing evidence for treatment of non war-affected

persons and the growing evidence for treatment of refugee populations” (Sonderegger et al., 2011, p. 236). It is currently unclear to what degree this empirically grounded treatment for PTSD should or would be effective with people from and in different cultures. This review summarises CBT interventions used in sub-Saharan Africa and explores their effectiveness.

### Outline of the Ehlers and Clark (2000) Model

The Ehlers and Clark (2000) model underlies PTSD CBT interventions, and is referenced in other intervention types including narrative exposure therapy or “NET” (Neuner, Schauer, Klaschik, Karunakara, & Elbert, 2004). The model outlines the maintenance of PTSD through the nature of the trauma memory and cognitive appraisals. PTSD becomes persistent when cognitive processing leads to a sense of serious, current threat. This is outlined in Figure 1 below.



**Figure 1 Ehlers and Clark (2000, p231) Cognitive Model of PTSD**

Starting with the appraisals of the trauma, these may be 1) overgeneralisations and overestimations of risks, 2) appraisals of one’s behaviour during the event, for example self-blame, 3) appraisals of the PTSD itself including the symptoms, such as one is going mad, 4) appraisals of the reactions from others, such as they no longer care and 5) appraisals of effects on health such as the belief one’s body is ruined. Appraisals can lead to perceived danger, maintaining an appraisal of current threat.

Second, the nature of the trauma memory is different. Intentional recall is impaired and unintentional recall, as intrusions or flashbacks, is experienced. Sensory and emotional re-

experiencing of the trauma event occurs *as if* the event were happening in the present. Stimuli relating to the trauma can trigger this, for example external cues such as smells or internal cues such as a particular posture. Trauma memories are not updated with any new information.

Improper formation of the trauma memory explains its unintentional recall. When normally processed, retrieval of memory is under control and embedded in the person's autobiographical memory. In PTSD, a lack of elaboration and integration of memory leads to their intrusive quality. The re-experiencing of danger memories then reinforces the negative appraisals and beliefs about current threat.

Third, strategies to manage appraisals of current threat maintain PTSD through 1) direct production of PTSD symptoms, for example thought suppression, 2) prevention of change of negative appraisals, for example engaging in safety behaviours, such as extreme vigilance that precludes the possibility of the person seeing that without such vigilance they remain safe, and / or 3) prevent change to the trauma memory, through avoidance of reminders that prevent elaboration of the trauma memory, thereby ensuring it remain decontextualized and prone to unintentional recall. As such, appraisals of threat and intrusions should be key features of PTSD, with emotional numbing (as a strategy) or emotional re-experiencing also seen. Ruminating on how the event could have been avoided may strengthen unhelpful appraisals. Beliefs may be disrupted, for example loss of belief in the world as just (Janoff-Bulman, 1992).

Memory processes may be disrupted or different to those without PTSD. Forgetting can be thought of as impaired in PTSD. Trauma memories are not forgotten but rehearsed through intrusions. "Retrieval induced forgetting" refers to how repeated retrieval of one memory can induce forgetting of related memories (Amir, Badour, & Freese, 2009). This effect has been observed with emotional memories (Barnier, Hung, & Conway, 2004). People with PTSD have been found to forget less easily in this paradigm (Amir et al., 2009). New but related information (current experience) does not cause the forgetting of previously learnt information (the trauma) as the trauma memory is not acting as a normal, embedded memory. Directive forgetting, similarly, is the ability to follow instructions to forget some items whilst remembering others. This is also impaired in PTSD, a further example of how forgetting is inhibited in PTSD (Cottencin et al., 2006). This provides further support for the hypothesised disruption of memory processes in PTSD, as integrated memory processes would lead to forgetting in these circumstances (Blix & Brennen, 2011).

### **Cultural Issues with PTSD Diagnosis and the Cognitive Model**

The majority of the research reviewed herein was conducted with reference to DSM-IV Revised criteria (American Psychiatric Association, 2000). These relate PTSD to exposure to a traumatic event that involved threat or actual significant injury to self or others and experienced intense fear, helplessness or horror. Symptoms and signs of PTSD itself are defined to include persistent re-experiencing, for example through nightmare or flashback and avoidance of thoughts, feelings, places and other stimuli associated with the trauma, with increased arousal. All this must occur for a least one month, cause significant distress or impaired functioning and not be explained by the presence of other disorders.

There are two principle critiques of the cultural applicability. First the very idea of *diagnosing* a response to a trauma may be adopting an unnecessarily pathological approach. Second the response to stress can be culturally specific in its experience and expression and therefore diagnosis cannot catch-all (Friedman, Resick, & Keane, 2007).

A review of the cross-cultural research around PTSD concluded that the studies were generally consistent with a universal biological response to trauma, with similar psychological symptoms, broadly supporting the description of PTSD as laid out in the DSM (Marsella, Friedman, Gerrity, & Scurfield, 1996). Symptoms may differ in terms of their salience such as the impact of somatic symptoms, appraisals of nightmares, and the perceived impact for example social meanings around shame and status (Hinton & Lewis-Fernández, 2011). However the existence of a distressing impact on functioning following trauma and covering “symptoms” or experiences similar to those set out in the DSM is supported cross-culturally (Hinton & Lewis-Fernández, 2011).

Understanding PTSD requires taking into account the wider socio-cultural environment. For people living in refugee camps or areas affected by war, on-going danger and stress is often present beyond the traumatic event(s). Structural violence such as persistent social inequalities, social deprivation and exclusion relevant to how trauma events in the past and present are experienced (Fernando, 2012). Further, items used in common assessment measures may be difficult to translate in terms of both semantic and conceptual equivalence, for example “numbing” symptoms of PTSD have proved difficult to translate (Fernando, 2012).

The applicability of the Ehlers and Clark (2000) model to non-Western contexts remains contentious. Appraisals of threat were observed in PTSD within collectivist cultures, although they focused on alienation (Jobson & O'Kearney, 2006), suggesting the model may need to incorporate more clearly interactions with others. Ideas around helplessness and appraisals central to the individual person may also differ as Western ideas about causality may not be shared in other

cultures. Ideas relating to fate or spiritual determination may already be present thereby perhaps lessening the impact of the destruction of ideas about a “just-world” (Janoff-Bulman, 1992). Additionally, for those from the inter-dependent cultures, mental defeat, beliefs about permanent change and control were not different between those with and without PTSD (Jobson & O’Kearney, 2009). A conceptual shift in emphasis from self-referenced appraisals to more socio-culturally referenced appraisal can thus be seen. This relates to the content of appraisals rather than the model’s proposed relationship between appraisals, perception of threat and experience of PTSD symptoms. This review then focuses on the processes outlined in the Ehlers and Clark (2000) model, rather than detailing associations between trauma experience and content of appraisals and PTSD symptoms.

No studies directly assessing the model’s applicability to African cultures could be found during preliminary literature searches, therefore studies addressing elements of the model require synthesis.

### **Review Research Questions**

This review aims to explore psychological models and interventions for PTSD in sub-Saharan Africa. Specifically:

1. To what extent are the processes in the cognitive model of PTSD (Ehlers & Clark, 2000) supported in studies using participants in sub-Saharan African?
2. What psychological interventions have been studied in sub-Saharan Africa? What theoretical orientation do these have? How have they been culturally adapted?
3. How effective are CBT interventions for PTSD in sub-Saharan Africa?

## **Methods**

### **Search Strategy**

Medline, PsycInfo, EMBASE and CINAHL were searched using the same terms. A sensitive search was chosen, listing all sub-Saharan African countries and simple post-traumatic stress disorder terms. Full search terms are given in Figure 2.

Angola OR Benin OR Botswana OR "Burkina Faso" OR Burundi OR Cameroon OR "Cape Verde" OR "Central African Republic" OR Chad OR Comoros OR "Republic of the Congo" OR "Democratic Republic of the Congo" OR "Cote d'Ivoire" OR "Ivory Coast" OR Djibouti OR "Equatorial Guinea" OR Eritrea OR Ethiopia OR Gabon OR Gambia OR Ghana OR Guinea OR "Guinea-Bissau" OR Kenya OR Lesotho OR Liberia OR Madagascar OR Malawi OR Mali OR Mauritania OR Mauritius OR Mozambique OR Namibia OR Niger OR Nigeria OR Rwanda OR "Sao Tome and Principe" OR Senegal OR Seychelles OR "Sierra Leone" OR "South Africa" OR "South Sudan" OR Sudan OR Swaziland OR Tanzania OR Togo OR Uganda OR Zambia OR Zimbabwe  
AND  
(PTSD or "traumatic stress" or "posttraumatic stress")

Figure 2 Search terms

Search terms could occur anywhere in the study. No date or language limits were placed on the results. Duplicates were rejected, retaining Medline records first, then PsycInfo, then EMBASE, then CINAHL. References from potentially relevant studies were then hand-searched and a cited reference search was conducted for each included study, to ensure inclusion of other relevant studies.

### Selection of Studies

The one broad search was used to generate potentially relevant studies for all three review questions. All results were assessed at title, abstract and then full-text stage for relevance for each research question. Two researchers independently scored all titles and abstracts for inclusion. Instructions were to include any studies that explored the process related to the PTSD model (i.e. cognitive processing during trauma, appraisal of events, nature of the trauma memory (e.g. intrusive memories), response to triggers, current sense of threat, strategies to control, for example research examining evidence of avoidance) and / or that researched a psychological interventions (see criteria below). The criteria listed below were shared with the co-authors and were used to guide decisions relating to inclusions / exclusions. Disagreements were discussed in relation to the review criteria, and revealed that it was important to include research with former child soldiers but not standard military.

For all aspects of the review, to be considered relevant, the study must provide data from non-Western participants from sub-Saharan Africa remaining in a sub-Saharan African context. Data could be from adults or children. Studies may provide data for more than one research question.

For research question one, studies were retained if they included findings around the Ehlers and Clark (2000) model, specifically information about the cognitive processes of PTSD, theories relating to PTSD with cognitive underpinnings and investigation or proposition of such frameworks



or models. At full-text stage, studies were excluded where no previously unreported data relating to any aspects of the model were provided.

For research question two, criteria to define intervention studies were informed by previous systematic reviews of PTSD interventions (Bisson & Andrew, 2007; Wampold et al., 2010). There has been substantial debate around what to include. Some reviews excluded treatments aimed at non-specific factors, such as a general relaxation training or supportive counselling and have specified that treatments must be delivered by Master's degree qualified therapists (Benish, Imel, & Wampold, 2008). Others have argued that supportive counselling represents a commonly used and theoretically grounded treatment (Ehlers et al., 2010). For this review, cultural, socio-political and economic realities of sub-Saharan Africa mean that gold standard treatment, for example qualified therapists, are unlikely to be available. Criteria were:

- Participants: multiple participants, no specific sample size criteria. Ideally, only participants with a diagnosis of PTSD should be included. However, given the cultural complexities and limitations around this diagnosis, studies were included where participants had been exposed to trauma or were experiencing symptoms.
- Intervention: Psychological treatment was defined broadly to include any "talking therapy" based on a psychological (including counselling) model or theory. Ideally interventions should be delivered by qualified therapists, however delivery by people trained in the intervention model only was minimum criteria. Group and individual interventions were included.
- Comparison group and study type: any controlled trial that considered one or more psychological treatment aiming to reduce traumatic stress symptoms in comparison with waitlist, usual care or alternative intervention fulfils the minimum criteria for this review. Ideally, studies should be randomised controlled trials.
- Outcome: Some element of PTSD symptom or diagnosis must be measured by a validated measure. Ideally any translated measures will also have been validated.

Initial decisions for inclusion were based on fulfilment of criteria for research questions one and two. For research question three, CBT studies were selected from the intervention studies in question two. To be categorised as CBT, primarily cognitive and/or behavioural techniques must be used (Bisson & Andrew, 2007), including exposure and cognitive restructuring. Individual and group approaches were considered (Regel & Berliner, 2007). Interventions could be of any length, however ideally should be multiple sessions (Bisson & Andrew, 2007). Interventions may include other elements in addition to CBT, such as life narrative writing.

### **Data Collection and Synthesis**

Data were extracted by two researchers independently and checked for inconsistencies. A data-extraction template was used (given in Appendix 1. No contact was made with authors. For research question one, information relating to any element of the Ehlers and Clark model was extracted in full. For example, any findings relating to the association of intrusive memories to reduced symptoms. For research question two, information as to the participants, study design, sample sizes, type of intervention and any comparison group, underlying theory, content and cultural adaptations was extracted. For research question three, results of intervention effectiveness were extracted and effect sizes were calculated.

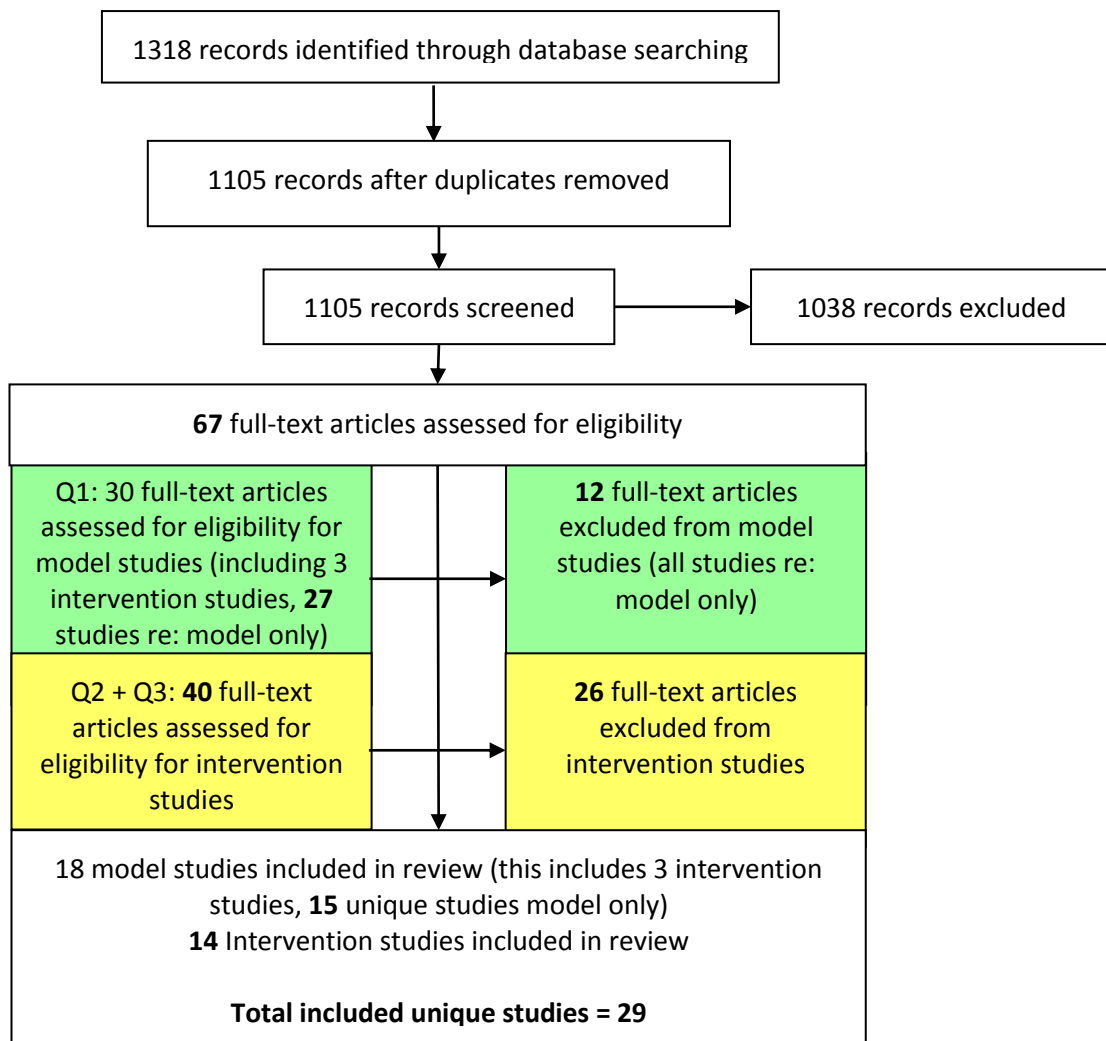
Data were synthesised, in the form of a critical narrative review. For research question three, a meta-analysis was conducted on the controlled and randomised-controlled studies. Owing to diverse measures used and aim to generate inferences, a random effects model was employed. Hedges g was calculated as standardised mean difference or “effect size” with weighted effect size (based on sample size). Hedges g effect size of 0.2 can be considered small, 0.5 medium and 0.8 large (Cohen, 1988). Analysis and forest plots were conducted using Review Manager 5 software (The Cochrane Collaboration, 2012). Many studies used intention-to-treat, however some reported only completer analysis. Subgroup analysis examined NET compared to studies described as CBT without the narrative component.

### **Risk of Bias**

For each study included in the meta-analysis, a risk of bias assessment was conducted using the tool developed by the Cochrane Collaboration (Higgins et al., 2011).

## **Results**

Figure 3 shows the flow of studies through the review. No additional studies were identified from the search of references and cited-reference searches of relevant papers. 26 unique studies were included in the review, with some overlap between studies for the three research questions.



**Figure 3 Results from the systematic review search and flow through the review**

### **Evidence Regarding the Ehlers and Clark (2000) Model**

Fourteen studies provided data about the model only, with an additional three intervention studies also providing information about the model. The findings are summarised in Table 1. The CBT interventions included for research questions two and three did not discuss the model, however it can be argued that the effectiveness of CBT interventions provides some support for the model, as this underlies much of the CBT content.

**Table 1 Summary of model related studies**

<b>Reference</b>	<b>Nation and sample</b>	<b>Study type</b>	<b>Model related finding</b>
Amone-P'olak, Garnefski & Kraaij (2007)	Uganda. Was traumatised adolescents.	Cross-sectional study	Rumination and avoidance are associated to PTSD symptom experience.
Bracken, Giller & Summerfield (1995)	Uganda. PTSD clinic patients.	Clinical observations.	Subjective meaning of events is key to trauma experienced. Appraisals of event link to PTSD experienced.
Eagle (2005)	South Africa, participants with PTSD.	Clinical observations.	Subjective meaning of trauma defines experience of PTSD. Appraisals of events are linked to PTSD.
Ensink, Robertson, Zissis & Leger (1997)	South Africa. Children with PTSD.	Cross-sectional	Intrusions, avoidance, re-experiencing and hyper-vigilance seen in PTSD.
Gregory & Embrey (2009)	Liberia. Former child soldiers.	Clinical observations.	Appraisals of on-going risk were seen prior to clinical intervention and therapy, which addressed these appraisals, was observed to reduce PTSD symptoms.
Koessler et al (2010)	Uganda. People with and without PTSD.	Experimental study	Retrieval-induced forgetting is inhibited, normal memory processes are not seen.
Magwaza (1999)	South Africa. People with and without PTSD from apartheid related trauma.	Cross-sectional/ between group study	Appraisals of the world are more negative and themed with threat.
McCall & Resick (2003)	Namibia. Kalahari" bushmen" with PTSD symptoms.	Cross-sectional.	Intrusions, hyper-arousal, hyper-vigilance observed along with re-experiencing when exposed to trauma-related stimuli.
Rasmussen, Smith & Keller (2007)	Participants with PTSD in Guinea, Sierra Leone, Mauritania, Cameroon, Democratic Republic of Congo (DRC), Togo and Liberia.	Cross-sectional, factor analysis.	Intrusions, hyper vigilance, numbness and avoidance all experienced by participants, relating to both PTSD symptoms and maladaptive strategies outlined in model.
Solomons (1989)	South Africa, ex-political detainees	Clinical observations.	On-going appraisal of current threat.
Vinson & Chang (2012)	Guinea and Sierra Leone, living in IDP camp	Cross-sectional, factor analysis.	Intrusions, hyper vigilance, numbness and avoidance all experienced by participants, relating to both PTSD symptoms and maladaptive strategies outlined in model.
Zwissler et al (2012)	Uganda. People with and without PTSD living in IDP camp.	Experimental study	Directed forgetting inhibited, revealing abnormal memory processing.

Reference	Nation and sample	Study type	Model related finding
Raby & Edwards (2011)	South Africa. Boy with history of abuse.	Case study	CATT, described as similar to CBT based on the model, was successful in treating a case, providing tacit support for the model.
Payne & Edwards (2010)	South Africa. 15 year old female rape survivor.	Case study	CBT based on the model successfully reduced PTSD symptoms.
Jordans, Komproe, Tol, Nsereko & de Jong (2013)	South Africa. Six children with PTSD.	Case series	Use of treatment strategies such as addressing of unhelpful appraisals, was associated to better outcome.
Neuner et al (2004)	Uganda. Sudanese refugees living in IDP camp	Intervention study	NET allows reconstruction of autobiographical memory and the effectiveness of intervention taken to support the model.
Onyut et al (2004)	Uganda. Somali refugee in IDP camp, children.	Intervention study	NET allows reconstruction of autobiographical memory and the effectiveness of intervention taken to support the model.
Sezibera, Van Broeck & Philippot (2009)	Rwandan adolescent survivors of 1994 genocide	Intervention study	Rumination focused intervention reduced PTSD symptoms, lending support for its causal role in PTSD.

**Nature of the trauma memory and memory processes in PTSD.** No studies specifically explored the nature of the trauma memory itself. However, two experimental studies did explore memory processes.

Retrieval-induced forgetting was impaired in those with a PTSD diagnosis compared to those without PTSD in a study in Uganda (Koessler et al., 2010). Again in Uganda, participants living in “internally displaced people” (or “IDP”, referring to those who have been forced to migrate within their own nation) camps completed a directed forgetting task (Zwissler et al., 2012). Participants with PTSD showed no effect of directed forgetting for stimuli that were emotionally evocative. This reveals different memory processes in people with PTSD, whether that be an impaired forgetting prior to PTSD or caused by the trauma. These studies support the idea that trauma memories are not integrated and processed like other memories, as laid out by the model.

**Appraisals of trauma.** Studies highlight the importance of the subjective nature of appraisals and their impact on experience.

In South Africa, ex-political detainees experiencing PTSD reported having believed they were going to die and being unable to influence the events in any way during the trauma (Solomons, 1989). Intrusions and on-going anxiety was observed despite cessation of threat. In another study, beliefs about the world in South Africans' with trauma experience during apartheid were compared to those without such experiences (Magwaza, 1999). Those who had been traumatised found the world to be less meaningful and experienced the environment as presenting threat, as well as experiencing low self-worth. A lack of meaning, increased belief in malevolence in the world, dissatisfaction with justice, on-going belief that one is at risk and that the world is unpredictable were all seen to a greater extent in interviews with those who had been traumatised compared to those who had not. Participants in Liberia expressed similar appraisals of on-going risk, which altered with therapy, alongside reduced PTSD symptoms (Gregory & Embrey, 2009). In a case series study, use of cognitive strategies to address negative interpretations of events was associated with good outcomes, where such strategies were indicated by the presentation (Jordans et al., 2013). Together these studies support the role of threat appraisals, which may be part of the subjective meaning of the trauma, in PTSD.

The observation of the appraisals alone cannot provide evidence for any causal role, however alteration of these appraisals through intervention which then reduces PTSD does suggest a causal role. These studies support the Ehlers and Clark model, as the model emphasises the personal appraisal as key to PTSD. Indeed, commenting on the model, Vickers remarked "What was new about this model when it was proposed was that it has cognitions and the personal meaning of events at its core, thus differing from previous 'conditioning' models of PTSD" (Vickers, 2005, p. 220) .

Individual experience and response may be objectively categorised as traumatic but may be subjectively experienced in a different way. For example, traumatic events may also be associated with strong religious experience and identification (Bracken et al., 1995). Eagle (2005) highlights the importance of cultural differences in notions of causality, with different beliefs around chance and the role of spirituality and witchcraft. Thus self-referential negative appraisals as part of a trauma response may be less relevant conceptually in the cognitive model of PTSD in sub-Saharan Africa.

**Current threat, intrusions and emotions.** This review does not include all studies that explored the content of PTSD symptoms, which relates to the experience of current threat. As described, this review focuses on the Ehlers and Clark (2000) model processes. However, four studies were included that also assessed the experience of PTSD and supported the presence of perceived current threat. All showed that intrusions, avoidance, re-experiencing and hyper-

vigilance were seen in PTSD (Ensink et al., 1997; McCall & Resick, 2003; Rasmussen et al., 2007; Vinson & Chang, 2012), as relating to the model.

**Strategies to control threat / symptoms.** As reviewed above, studies revealed problematic cognitive strategies predicted by the model, such as avoidance, numbing of emotion and checking. In addition, rumination was investigated in two studies. The Ehlers & Clark (2000) model states the negative evaluations, unintegrated trauma memory and appraisals that lead to dysfunctional coping drive the PTSD, with anxious ruminations maintaining this process (Wells & Sembi 2004). PTSD symptoms were correlated with rumination ( $r=0.14$ ,  $p<0.05$ ) and “denial” ( $r=0.32$ ,  $p<0.01$ ), which covered avoidance, in a sample of war traumatised adolescents in Uganda (Amone-P'olak et al., 2007). The success of a rumination focused intervention, that reduced rumination and PTSD symptoms, provides quasi-experimental support for rumination as a causal mechanism within PTSD (Sezibera et al., 2009).

**Overall model.** Four studies drew on the effect of interventions to provide evidence for the model. Two NET studies discuss how the therapy works by addressing the reconstruction of autobiographic memory and establishment of a consistent narrative to address the fragmented memory (Neuner et al., 2004; Onyut et al., 2004). The success of the interventions is taken as tacit support for the theory regarding the importance of the memory processes. The “Children’s Accelerated Trauma Treatment” is described as based on Ehlers & Clark (2000), with CBT case formulation used as part of the approach (Raby & Edwards, 2011). Success of the intervention provides potential support for the model. Finally, cognitive therapy was delivered to a 15 year old rape survivor (Payne & Edwards, 2010). The treatment used a formulation based on the model, and the report provides evidence for “the transportability of the Ehlers and Clark model” (Payne & Edwards, 2010, p. 36). The effectiveness of CBT studies, reviewed shortly, also provides support.

### **Interventions Used and Cultural Adaptations Made**

The intervention studies are summarised in Table 2, which details sample, study design and details of interventions. This includes all psychologically based interventions.

**Table 2 Intervention studies included in the review – details of sample, design, intervention and outcomes measured**

<b>Study</b>	<b>Nations where data collected</b>	<b>Sample details</b>	<b>Study design</b>	<b>Intervention and comparison type</b>	<b>Intervention structure</b>	<b>Details of other inclusion criteria</b>
Bass et al (2013)	DRC	Survivors sexual violence	RCT, (Randomised by village unit) Baseline, post-intervention and 6 month follow-up	Cognitive processing therapy (CT) (n=127) Compared to “individual support” (n=248).	CT comprised one individual session and 11 group sessions. Individual support comprised of availability of “psycho-social assistant” for women to seek support from.	<u>Diagnosis:</u> PTSD Checklist - Civilian Version indicated probable PTSD rates in 60% of therapy group and 83% of the control group at baseline. <u>Therapist:</u> Psychosocial assistants who completed 2 weeks of training in the US in the use of the intervention manual. <u>Outcome measure:</u> PTSD Checklist – Civilian (PCL-C) Version, good psychometric properties in translation.
Connolly & Sakai (2011)	Rwanda	Genocide survivors	RCT Baseline, post-treatment, 2 year follow-up	Thought Field Therapy (n=71, 57 attended treatment, 36 completed post-treatment) Compared to WLC (n= 74, 49 provide post-treatment data)	Individual intervention. One session, mean duration 41 minutes.	<u>Diagnosis:</u> Unclear, states all clients met the DSM-IV criteria, although this appears to be based on the idea that exposure to trauma is sufficient. <u>Therapist:</u> Local lay therapists trained for 2 days in TFT. <u>Outcome measure:</u> Modified PTSD Symptom Scale. Translated to Kinwarwanda, no psychometrics reported.



Study	Nations where data collected	Sample details	Study design	Intervention and comparison type	Intervention structure	Details of other inclusion criteria
Ertl, Pfeiffer, Schauer, Elbert & Neuner (2011)	Uganda	Former child soldiers	RCT Baseline, 3 months, 6 months and 12 month follow-up.	NET (n=29) Compared to academic catch-up with supporting counselling (n=28) or WLC (n=28)	Individual sessions. All received psycho-education on PTSD symptoms and consequences. Both interventions 8 sessions of between 90 and 120 minutes, three times a week.	<u>Diagnosis:</u> Used CAPS and revised DSM-IV to assess for PTSD symptoms, does not report % participants with diagnosis. <u>Therapist:</u> Intensively trained lay counsellors <u>Outcome measure:</u> CAPS*, no details of any translation
Igreja, Kleijn, Schreuder, Van Dijk & Vershuur (2004)	Mozambique	Civil war survivors	RCT Baseline and 11 month follow-up	Testimony therapy (n=66) Compared to control group, receiving no intervention (n=71) or a non-case group receiving no intervention (n=69).	Testimony with individual and their household. For 59 participants one 60 minute session, for remaining 7 participants two sessions.	<u>Diagnosis:</u> Used baseline measurements as cut-off point of symptoms to create a case and control group, however it is not clear how relates to clinical diagnostic levels. <u>Therapist:</u> No stated. <u>Outcome measure:</u> Self-Inventory for PTSD, good internal consistency reported.
Lekskes, van Hooren & de Beus (2007)	Liberia	Female victims of war-related and sexual violence	CT Baseline and “post” intervention	Community based counselling, or “CCC” (n=34) Compared to WLC (n=10) [They included another intervention but this was socio-economic in focus rather than psychological].	CCC included typically 8 individual counselling sessions and group counselling (no details) over three months.	<u>Diagnosis:</u> CCC group had 69% with diagnosis whereas control had 14% only. <u>Therapist:</u> Auxiliary medical personal and local counsellors. <u>Outcome measure:</u> HTQ, no psychometric properties of translation provided.

Study	Nations where data collected	Sample details	Study design	Intervention and comparison type	Intervention structure	Details of other inclusion criteria
McMullen, O'Callaghan, Shannon, Black & Eakin (2013)	DRC	Former child soldiers and other war-affected boys, aged 13-17	RCT Baseline, post-intervention and 3 month follow-up	CBT (n=25) Compared to WLC (n=25)	CBT was culturally adapted. 15 session duration, 2-4 individual sessions, remainder in group.	<u>Diagnosis:</u> No diagnosis or screening, recruited owing to war experience. <u>Therapist:</u> Two Western Educational, Child and Adolescent Psychologists with two local lay facilitators. <u>Outcome measure:</u> UCLA-PTSD RI, good psychometric properties.
Neuner et al (2008)	Uganda	Refugees from Rwanda and Somali living in camp in Uganda	RCT Baseline, post-intervention and 9 month follow-up.	NET (n=111) Compared to trauma counselling (n=111) or WLC (n=55)	Individual therapy. 6 sessions of NET or 6 sessions of trauma counselling. Sessions 2 hours long.	<u>Diagnosis:</u> All participants fulfilled DSM-IV criteria, assessed using the PDS (Posttraumatic Stress Diagnostic Scale) <u>Therapist:</u> Refugees trained as counsellors in 6 week general counselling skill and NET course. <u>Outcome measure:</u> PDS, previously validated versions.
Neuner, Schauer, Klaschik, Karunakara & Elbert (2004)	Uganda	Sudanese refugees living in camp	RCT Baseline, post-treatment, 4 month follow-up, 12 month follow-up	NET (n=17) Compared to supportive counselling (n=14) or psycho-education (n=12)	4 NET sessions (individual) or 4 sessions supportive counselling (group) or 1 session psycho-education (group)	<u>Diagnosis:</u> All participants had PTSD according to DSM-IV criteria, CIDI interview also used. <u>Therapist:</u> Doctoral level psychologists or graduate students with experienced in other treatment approaches. <u>Outcome measure:</u> PDS, translated into local Arabic dialect. No psychometrics reported.

Study	Nations where data collected	Sample details	Study design	Intervention and comparison type	Intervention structure	Details of other inclusion criteria
O'Callaghan, McMullen, Shannon, Rafferty & Black (2013)	DRC	Sexually exploited war-affected girls	RCT Baseline, post-intervention and 3 month follow-up	CBT (n=24) Compared to WLC (n=28)	CBT was group based and "culturally modified". Sessions two hours long, 3 days per week for five weeks.	<u>Diagnosis:</u> No reference to diagnosis is made, nor screening on the basis of any specific criteria to identify PTSD, rather recruits participants who have experienced sexual abuse. <u>Therapist:</u> Social workers employed by NGO, given training and intervention manual. <u>Outcome measure:</u> UCLA-PTSD RI, good internal consistency reported.
Pokariyal, Runo & Munywoki (2013)	Kenya	Victims of torture who are citizens of Kenya.	CT Baseline and "post" intervention	"Multisensory trauma processing" (MTP) And / or "Conventional therapy". (See right for details.)	MTP and conventional treatment had variable numbers of sessions, with several participants receiving both. Only 9 participants received only MTP (between 4 and 6 sessions), 21 receiving only conventional intervention (between 6 and 30 sessions) and 22 received both (MTP between 2 and 9, conventional between 1 and 6).	<u>Diagnosis:</u> Diagnosis of PTSD was given to 30 participants, unclear how arrived at. <u>Therapist:</u> No details provided. <u>Outcome measure:</u> SSI, no psychometric properties reported.

Study	Nations where data collected	Sample details	Study design	Intervention and comparison type	Intervention structure	Details of other inclusion criteria
Rees, Travis, Shapiro & Chant (2013)	Uganda	Refugees from DRC exposed to war violence living in camps in Uganda	RCT Baseline, 30 day and 135 day post-tests	Transcendental Meditation (n=21) Compared to WLC (n=21)	Transcendental meditation delivered in several sessions: 1 hour introduction, 1.5 hours personal instruction, three 2 hour follow-up meetings and optional weekly follow-up group meetings of 1 hour each.	<u>Diagnosis:</u> PCL-C scores similar between the groups however no reference is made to whether these levels signify possible diagnosis. <u>Therapist:</u> Certified African transcendental meditation teachers. <u>Outcome measure:</u> PCL-C, no psychometric properties of translations provided.
Schaal, Elbert & Neuner (2009)	Rwanda	Rwandan genocide orphans, aged between 14 – 28 (mean 19.42, s.d. 3.59)	RCT Baseline, post intervention and 6 month follow-up.	NET (n=12) Compared to interpersonal psychotherapy or IPT (n=14)	NET which included 3 NET sessions and only grief session derived from IPT. All individual therapy. IPT comprised of 4 group sessions (single gender).	<u>Diagnosis:</u> 100% participants selected on basis fulfilling PTSD diagnosis based on DSM-IV. <u>Therapist:</u> 2 trained counsellors from European university. Weekly supervision. Interpreter used. <u>Outcome measure:</u> CAPS, no details of any translation given, no psychometric properties reported.

Study	Nations where data collected	Sample details	Study design	Intervention and comparison type	Intervention structure	Details of other inclusion criteria
Sonderegger, Rombouts, Ocen & McKeever (2011)	Uganda	War affected in IDP camps	RCT (not randomised individually but selected camps to be either treatment or control) Baseline, post-treatment and 3 month follow-up.	CBT (n=90) Compared to WLC (n=112).	A culturally adapted CBT was delivered in a group. 13 two hour sessions.	<u>Diagnosis:</u> War affected persons, no diagnosis of PTSD <u>Therapist:</u> Facilitators received “comprehensive” training in CBT and intervention use from a Clinical Psychologist from the West. <u>Outcome measure:</u> Acholi Psychosocial Assessment Instrument – anxiety-like syndromes relating to element of PTSD. Locally developed in previous research.
Yeomans, Forman, Herbert & Yuen (2010)	Burundi	IDPs in rural Burundi	RCT Baseline (6 weeks prior to intervention) and post-intervention (2 weeks after end)	Workshop with psycho-education (n=38) Compared to workshop alone (n=37) or Wait List Control (WLC) (n=38)	Group interventions – both 3 days continuously then 1 month later a full-day.	<u>Diagnosis:</u> No formal diagnosis, included on basis of trauma experience. <u>Therapist:</u> Local facilitators trained for one day to deliver the group intervention <u>Outcome measure:</u> HTQ translated into Kirundi and back translated, good internal consistency reported.

\*Measures are described in full in Table 3

**Intervention type.** Fourteen intervention studies were included. Clarification of content is needed. CBT interventions are those that directly address elements of the Ehlers and Clark (2000) model by using cognitive techniques such as restructuring of threat appraisals and / or behavioural techniques such as exposure to the trauma memories or specific trauma related situations or stimuli (Zayfert & Becker, 2007). Narrative exposure therapy (NET) is short-term intervention, developed for use in low-resource countries, for survivors of multiple traumas. It involves the creation of a chronological account of biography with detailed reconstruction of fragmented trauma memories in order to achieve habituation (Ertl et al., 2011; Robjant & Fazel, 2010). NET is characterised by some as a form of CBT (Dossa & Hatem, 2012). As the intervention involves exposure and cognitive challenge (Schauer, Neuner, & Elbert, 2005), it can be thought of as a type of CBT.

Testimony therapy referred in this case (Igreja et al 2004) to the production and reading of a testimony, which may fall into an exposure type of intervention, but is less clearly defined and cannot be thought of as a CBT intervention. Meditation is also not a CBT type intervention. “Thought Field Therapy” (TFT) is described as a brief self-help treatment, composed of client engaging in exposure to thoughts of the trauma and associated feelings whilst engaging in tapping their skin in areas thought to be specifically linked to specific emotions (Connolly & Sakai, 2011). TFT cannot be thought of as CBT as the proposed main mechanism of action appears to be using acupuncture points that are associated with the emotion (Callahan, 2001). “Multisensory trauma processing” (Pokhariyal et al., 2013) cannot be thought of as CBT as this includes elements of tapping and eye-movement desensitization therapy, that assume action on the hippocampus and an active element of rapid eye-movement.

There were four interventions describing themselves as CBT. First, in Uganda, a group intervention with war affected people living in IDP camps included trust building exercises, goal setting, psycho-education, skills for identification of physical response to stress and control of this, relaxation techniques, protective behaviour development, cognitive work challenging negative thoughts, introduction of concepts of forgiveness and reconciliation and work towards letting go of past trauma. One-to-one trauma memory identification was also conducted (Sonderegger et al., 2011). Second, in the Democratic Republic of Congo (DRC), a group CBT intervention of 15 sessions over three weeks was completed with sexually exploited, war affected girls (O’Callaghan et al., 2013). This included psycho-education, stress management with relaxation, expression and modulation of emotions, basic CBT formulation linking thoughts, feelings and behaviours and identification of unhelpful thoughts. The intervention was supplemented by sessions with care-givers to provide them with education about PTSD and parenting methods. Again in the DRC, a cognitive processing therapy (CPT) intervention used cognitive methods only (Bass et al., 2013). The study did not describe the intervention in detail, however referred to pre-existing studies that

describe the intervention as including education, exposure and work on maladaptive cognition identification and replacement (Resick et al., 2008; Resick & Schnicke, 1992). Exposure is not considered as the mechanism for change although may take place during cognitive processing. The final CBT study in the DRC was with former boy child-soldiers or otherwise affected by war assessed a mixed individual and group intervention over 15 sessions (McMullen et al., 2013). Psycho-education, stress management, affect expression and modulation, cognitive coping with basic formulation and thought challenging and discussion of future hopes were included.

Four NET interventions were identified. In Uganda, 4 sessions of NET were given to Sudanese refugees living in IDP camps (Neuner et al., 2004). This included psycho-education, creation of an autobiography, embedding the trauma into the narrative, elicitation of emotional, cognitive, physiological and behavioural responses, reliving and writing a biography. Similar content was used in the second intervention in Uganda: an 8 session NET intervention delivered in 90-120 minute sessions, three times a week to former child soldiers (Ertl et al., 2011). A third NET intervention offered six sessions of individual therapy in Uganda was carried out with refugees from Rwanda and Somali living in IDP camp in Uganda (Neuner et al., 2008). In Rwanda, three sessions of NET with one session of interpersonal therapy (IPT) grief work was delivered to Rwandan genocide orphans (Schaal et al., 2009). The NET content was based on those previously outlined, with the IPT session included because of the prevalence of grief and facilitated remembering of the deceased person.

The remaining interventions had varied content. First, in Rwanda, one session of TFT was delivered to adult genocide survivors (Connolly & Sakai, 2011). Rwandan therapists were trained to deliver the treatment, involving elicitation of subjective units of distress around memory recalls and acupuncture intervention. Second, psycho-education, teaching on coping skills and relaxation and discussion of repairing relationships in Burundi was completed with IDPs over three consecutive days (Yeomans et al., 2010). Third, in Mozambique, a “Testimony therapy” intervention was used with civil war survivors (Igreja et al., 2004). The participant’s testimony was recorded through an interpreter and read to the family. The intervention description does not indicate any cognitive intervention. Fourth, in Uganda, “Transcendental meditation” was offered to refugees from DRC exposed to war violence, living now in IDP camps (Rees et al., 2013). The meditation was delivered in groups over five sessions, including some personal instruction. In addition, participants could attend weekly follow-up groups, one hour in duration. A counselling intervention, including group and individual sessions, was delivered in the community to female victims of war-related and sexual violence (Lekskes et al., 2007). No theoretical underpinnings of details of the therapy approach were given. Finally, a multisensory trauma processing intervention was tested (Pokhariyal et al., 2013). This intervention borrows from both cognitive therapy

approaches and eye-movement desensitisation therapy (Shapiro & Solomon, 1995) and was based on the idea that PTSD is a biologically based disorder.

**Participants' diagnosis.** As detailed in Table 2, the presence of diagnosis was not typically reported. Some studies used inclusion criteria of exposure to trauma only, rather than presence of significant distress.

**Therapist.** As detailed in Table 2, only four studies used professionally trained therapists. The level of detail reported in the studies was typically scant.

**Outcome measures.** All studies were included based on satisfaction of the criteria of using validated measures. The measures used are displayed in Table 3. Nine different measures were identified. All but two (APAI and SSI) clearly assess aspects identified in the DSM-IV description of PTSD. The APAI provides a measure of locally defined mental health difficulties for use in Uganda. The concept of “*ma lwor*” includes elements of anxiety more generally, in addition to features of PTSD around current threat, for example, and is therefore considered a measure of a construct aligned to PTSD (Betancourt, Speelman, Onyango, & Bolton, 2009b). CBT studies using the APAI measure are therefore eligible for inclusion in the meta-analysis in terms of adequate measure used.

**Table 3 Descriptions of PTSD measures used in intervention studies**

Measure	Description
Harvard Trauma Questionnaire or HTQ	Assesses impact of the seventeen symptoms listed in the DSM-IV for PTSD and was designed for use with refugees (Mollica et al., 1992). The properties of this measure has been explored amongst African participants with PTSD and although the measure had good properties (Rasmussen et al., 2007), the best fit divided hypervigilance into its own factor, combined other hyperarousal symptoms with intrusions and preserved numbness and avoidance as two separate factors (Rasmussen et al., 2007). This is different from the DSM-IV structure of three factors of hyperarousal, avoidance/numbing and intrusion.
Self Inventory for PTSD or SIFP	Developed as a self-administered questionnaire, SIFP has four factors (numbing, intrusion, avoidance and sleeping problems) mirroring the DSM and was found to have good validity compared to various other PTSD measures, including the CAPS and MPSS (Hovens et al., 1994).
Post-traumatic stress diagnostic scale or PDS	Respondents rate exposure to trauma, symptom experiencing and impairment of functioning as set out by the DSM-IV criteria. The PDS was validated against structured clinical interview to identify a clinical cut-off put to indicate diagnosis (Foa, Cashman, Jaycox, & Perry, 1997).
Clinician Administered PTSD Scale or CAPS	CAPS must be completed with structured clinical interview, covering the symptoms outlined in the DSM (in this case the earlier version III-R) and assessing impact on functioning, overall severity and changes over time (Blake et al., 1995)
Modified Posttraumatic Stress Disorder Scale or MPSS	This assesses frequency and severity of the seventeen PTSD symptoms using a self-report questionnaire (Falsetti, Resnick, Resick, & Kilpatrick, 1993).



Measure	Description
PTSD Checklist – Civilian Version or PCL-C	The measure elicits symptom ratings for each of the seventeen PTSD symptoms (Weathers, Huska, & Keane, 1991). This measure has been extensively used with a score typically over 50 (out of 85, higher scores showing more symptoms) indicating suggested diagnosis (Brewin, 2005).
University of California at Los Angeles Posttraumatic Stress Disorder Reaction Index or UCLA PTSD RI	UCLA PTSD RI is a self-report measure assessing both exposure to trauma and symptoms, for use with children and adolescents (Steinberg, Brymer, Decker, & Pynoos, 2004). A three factor solution best fit data taken from a large study in the United States and differed from the DSM suggested structure, mixing intrusive symptom with avoidance/numbing symptoms across the factors (Steinberg et al., 2013).
Acholi Psychosocial Assessment Instrument or APAI	The APAI was developed in Uganda to reflect locally relevant psychological difficulties (Betancourt et al., 2009a), with the dimension of anxiety-like symptoms most closely relating to the Western PTSD construct, including items around over-sensitivity to noise, hyper-arousal, beliefs about current danger relating to being chased and symptoms of anxiety such as rapid heart rate.
Stress State Inventory or SSI	No reference given and no details of the measure presented in the paper that used this instrument (Pokhariyal et al., 2013).

Seven studies reported at least good (around 0.7) internal consistency of their measures (or referenced studies that validated the version being used). No details of translation properties were given in the remaining papers.

**Cultural adaptations.** Two NET studies stated the intervention was designed for resource-limited or war-affected regions (Neuner et al 2004, Neuner et al, 2008). The narrative approach uses story-telling, which is common in many African cultures, supporting the use of Testimony Therapy also (Igreja et al., 2004).

Cultural adaptations were described in four CBT studies (Bass et al., 2013; McMullen et al., 2013; O'Callaghan et al., 2013; Sonderegger et al., 2011) and one psycho-education study (Yeomans et al., 2010).

Bass et al (2013) describe in detail their adaptation to cognitive therapy to increase cultural relevance and accessibility to illiterate participants. Psycho-education sessions addressed expectations and rationales for talk therapy. Homework assignments were simplified to allow easy remembering and oral reporting. Technical language was reduced and images used in worksheets. Beliefs about the effect of rape on social status were taken into account when doing cognitive restructuring. Socratic questions were used to investigate potential flexibility, for example on whether *all* the family felt ashamed of the person who had been raped, or if there was some who did not.

Familiar stories, games and metaphors were used to explain CBT concepts in several studies (McMullen et al, 2013, O’Callaghan et al 2013). Local animals and food were used in the imagery for relaxation and fear of animals used to explain intensity of feelings (McMullen et al, 2013). Story-telling, physical activities and games were used to increase acceptability, as talk therapies are less known and accepted. Local facilitators and language were used in delivery (McMullen et al, 2013, O’Callaghan et al 2013 and Sonderegger et al 2011).

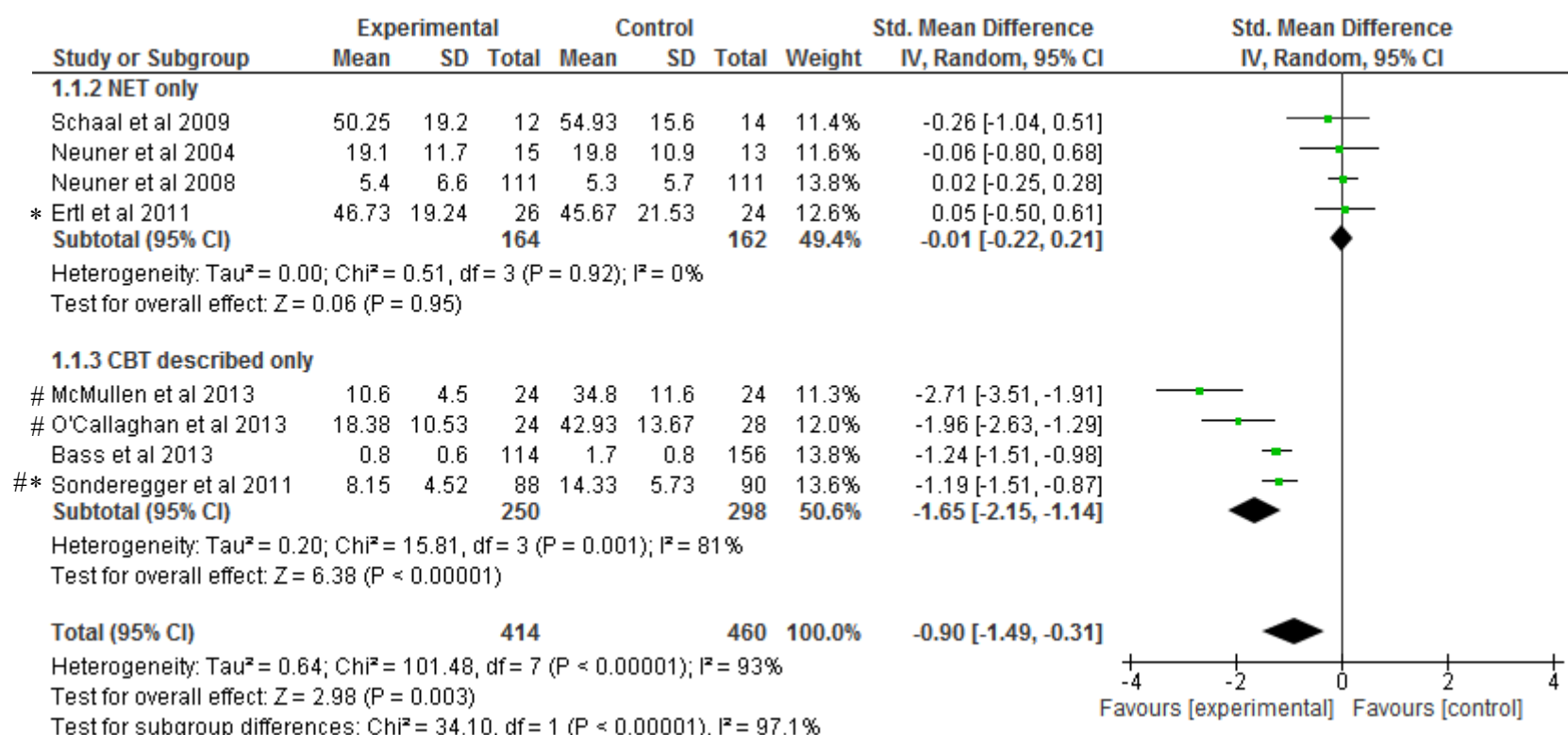
Elements of process were adapted in two interventions. Sonderegger et al (2011) limited the amount of open disclosure of highly traumatising events in the group, not only to avoid re-traumatisation but also to reduce the description of events that may lead to stigma. Yeomans et al (2010) describe their emphasis on recovery of community relationships and importance of neighbour to neighbour reconciliation, relating to a more collectivist culture.

### **Evidence of Effectiveness of CBT for PTSD in Sub-Saharan Africa**

Four studies were standard CBT and four were NET, which can be thought of as a type of CBT. All eight reported post intervention scores for their PTSD measure, allowing meta-analysis of effectiveness. Six studies reported means and standard deviations for the follow-up data collection. Table 4 summarises the comparisons used, whilst Figures 4 and 5 below provide the forest plots and analyses. All studies were RCTs, although Sonderegger et al (2011) and Bass et al (2013) randomised at the level of IDP camp or village. A random effects model was used, owing to the heterogeneity. Owing to the small number of included studies, results should be interpreted with caution.

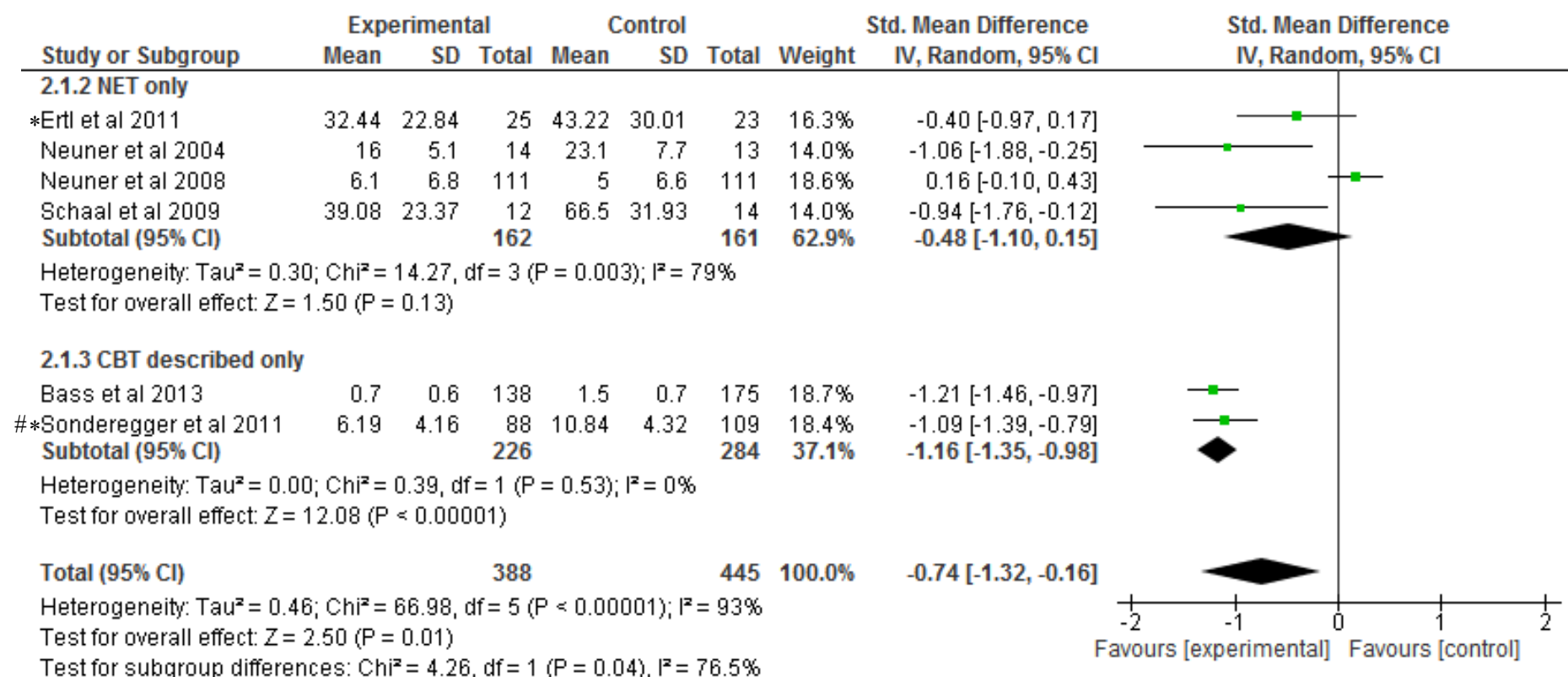
**Table 4 CBT studies included in meta-analysis**

<b>Study</b>	<b>Intervention described as</b>	<b>Comparison</b>	<b>Outcome Measure</b>	<b>Follow-up data provided</b>
Neuner et al 2004	NET	Supportive psychotherapy	PDS	12 months
Ertl et al 2011	NET	Supportive counselling	CAPS	12 months
Neuner et al 2008	NET	Unstructured counselling	PDS	9 months
Schaal, Elbert & Neuner 2009	NET	Interpersonal therapy	CAPS	6 months
Sonderegger et al 2011	CBT	Wait List Control (WLC)	APAI	3 months
O’Callaghan et al 2013	CBT	WLC	UCLA-PTSD RI	Mean and s.d.not provided
McMullen et al 2013	CBT	WLC	UCLA-PTSD RI	As above
Bass et al 2013	CBT	Individual support	PCL-C	6 months



\*Indicates study did not blind assessor to intervention group  
# Indicates wait-list control only, no active control group used

**Figure 4 Post Intervention Comparisons Forest Plot**



\*Indicates study did not blind assessor to intervention group

# Indicates wait-list control only, no active control group used

**Figure 5 Follow-up Comparisons Forest Plot**

Overall, CBT type interventions appear to have a statistically significant effect at post-intervention ( $Z=2.98$ ,  $p=0.003$ ) and at follow-up ( $Z=2.50$ ,  $p=0.01$ ), however this is based on a small number of studies that have considerable heterogeneity ( $\text{Tau}^2=0.64$  and  $0.46$  respectively,  $I^2=93\%$  for both). Standardised mean differences (Hedges  $g$ ) demonstrate wide ranges, within the 95% confidence interval for the summary statistics. The studies differ in measure used, comparison group, participants and intervention details.

Subgroup analysis revealed significant differences for post comparisons ( $p<0.00001$ ) and follow-up ( $p=0.04$ ). NET interventions achieved smaller effect sizes that did not indicate effectiveness (for post comparisons  $Z=0.06$ ,  $p=0.95$  and for follow-up  $Z=1.50$ ,  $p=0.13$ ).

A summary of risk of bias analysis is presented in Table 5.

**Table 5 Risk of bias analysis**

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Bass et al (2013)	+	-	-	-	+	+	?
Ertl et al (2011)	?	?	-	+	+	+	+
McMullen et al (2013)	+	+	-	+	+	+	?
Neuner et al (2004)	+	+	-	+	+	+	?
Neuner et al (2008)	+	+	-	+	+	+	?
O'Callaghan et al (2013)	+	+	-	+	+	+	?
Schaal et al (2009)	+	+	-	+	+	+	+
Sonderegger et al (2011)	?	?	-	-	-	+	?

**Key:** +Low risk of bias, - High risk of bias, ? Unclear risk of bias

Reasons for other bias concerned the inclusion of participants in the trial who may not have had PTSD and a lack of detail regarding potential therapist effects, such as number of interventions provided by specific therapists. The high level of bias relating to blinding of participants and staff relates to a common problem in psychological intervention research, whereby the staff and participants are aware of the intervention delivered.

## Discussion

### Model

Eighteen papers relating to the CBT model of PTSD and providing data from sub-Saharan Africa were identified. All provided support for elements of the model. There were no studies identified

that explicitly set out to test the model, nor studies that explored all elements of the model. In several cases, the presence of appraisals or reduction of symptoms was taken as support for the model, despite other possible explanations. For example, the causal role of appraisals is not explored – appraisals may be present however not causing PTSD to be maintained. Further, non-specific elements of intervention, such as someone bearing witness to a person's testimony, may be impacting on the PTSD symptoms, rather than the model specific elements.

Research identified discussed the differences in trauma related appraisals. Further research could explore whether there are some appraisals that are specific to PTSD and the degree to which these specific appraisals differ cross-culturally.

### **Interventions**

Fourteen eligible intervention studies were identified. There were many differences between the intervention content, comparison, participants, therapists, outcome measures and cultural adaptations.

CBT interventions include elaborations such as discussion of forgiveness and reconciliation (Sonderegger et al 2011). Furthermore, descriptions of some interventions are not detailed. NET interventions are the exception, as these are manualised (Schauer et al., 2005). The meditation intervention included some personal instruction and groups (Rees et al 2013). It is not clear what was included in these sessions. They may have involved basic cognitive work or social support that may be responsible for any improvement, rather than the meditation. It is not possible to specify which intervention components are more or less appropriate or lead to better or worse outcomes.

Seven of the fourteen intervention studies compared against a wait list control. Further use of active control groups is required to improve study quality and conclusions that can be drawn. Twelve studies described using randomisation, which helps reduce the risk of bias in results. The review criteria led to exclusion of several pre-post studies, which may provide useful information as to the acceptability, process and feasibility of intervention delivery.

Although there are potential limitations with the cultural applicability of the diagnosis and description of PTSD, the inclusion of participants in PTSD treatment merely on the grounds of exposure to trauma must be called into question. Not only does this represent a threat to the validity of research findings, the delivery of PTSD treatment to those who are not displaying symptoms or distress may be unethical. Inclusion in unnecessary treatment is not advised. Furthermore, provision of this treatment may be harmful to those not displaying symptoms or distress (Mayou,

Ehlers, & Hobbs, 2000), and is unlikely to be effective in preventing development of PTSD (Rose, Bisson, Churchill, & Wessely, 2002).

The therapists used were frequently not qualified formally. There is a complex trade-off between having a local, culturally skilled person trained to deliver the intervention versus having a perhaps more technically skilled trained therapist. Further research should explore the degree to which training “lay” therapists is as effective as using formally qualified therapists. In order to achieve this, studies must start reporting clearly the training provided. This is pertinent given the lack of qualified mental health professionals, for example there are 1.13 human resources per 100,000 people in Uganda (WHO, 2006).

A wide-range of measures were identified. It is imperative now to ensure adequate psycho-metric properties of translations. Measures were largely derived from DSM criteria. It may be important to explore local understandings of PTSD and incorporate these items into measures.

Cultural adaptations were described, focusing on mode of delivery and some elements of content. The acceptability and fit to the participants’ literacy levels and local customs is the main focus. The processes of therapy, working on cognitions and behaviours, are not adapted. One issue that was rarely addressed was the belief that therapy can cause change in experience. It may be that for some cultures, beliefs about causality may be around fate and spirits, creating a potential barrier for intervention.

### **CBT effectiveness**

Eight studies were defined as CBT based interventions. Meta-analysis revealed considerable heterogeneity but indicated probable effectiveness. The degree to which these effect sizes represent a meaningful clinical difference remains unknown and requires further work. Subgroup analysis revealed NET studies were not effective whilst studies described as standard CBT were at both post-intervention and follow-up. The conclusions from this must be tentative as studies used a variety of samples, CBT content and included control groups. Risk of bias was generally low for the studies, however the issue of no blinding for personnel and participants as to the type of intervention received has not been addressed. This issue, common to many therapy trials, limits conclusions about the effectiveness owing to potential bias (Lynch, Laws, & McKenna, 2010). There is a significant risk of publication bias, as all studies reported somewhat positive results, suggesting there are some missing studies. Furthermore, three of the four standard CBT studies included in post-intervention analysis did not have an active control group, whereas the NET studies all included an active control group. This may lead to overestimation of the effectiveness of

standard CBT as compared to the NET studies. Further studies should compare CBT to an active control group.

### **General observations**

As observed, the interventions are generally not described in detail and it is current not clear which components may be effective or necessary. Owing to similar difficulties in health psychology interventions, a taxonomy of behavioural change techniques has been developed to encourage researchers to clearly describe the intervention contents and to allow literature reviewers to analyse outcomes in relation to intervention content (Abraham & Michie, 2008). A similar approach to CBT and other clinical psychology techniques may be beneficial.

The important question relating to which parts of intervention are required to be effective cannot be answered. This question is particularly pertinent given the importance of having a maximally effective intervention with the minimum resource use, owing to the resource limited setting and great impact of PTSD in the region.

The necessity for intervention addressing cognitions or behaviours or both is questioned in CBT research (Butler, Chapman, Forman, & Beck, 2006). The studies identified here did not explore changes in proposed mechanisms, such as cognitive variables like catastrophic interpretation of intrusions or behavioural variables like avoidance. As such, it is not clear which components are most a) important in maintaining PTSD or b) most acceptability targeted by intervention.

### **Limitations**

This review is limited by focusing only on published research. There is a considerable risk of bias owing not only to less than gold-standard research design but also as all studies support interventions. There is likely to be a substantial dataset from monitoring and evaluation of charities delivering interventions in the region. The lack of inclusion of this data limits the review conclusions as field-data may provide a more ecologically valid representation of the effectiveness of the interventions and would increase the sample size included in the review. However, it is unlikely that data from the service delivery organisations such as charities would be of sufficient methodological quality to include in a meta-analysis. Furthermore, there is a lack of interaction between the charity stakeholders and researchers. In order to deliver the best possible interventions, it may be beneficial for this interaction to take place to interrogate the evidence base to inform policy, funding and practice.

The meta-analysis is limited by heterogeneity between the studies and a small number of interventions. Heterogeneity statistics show high heterogeneity, therefore it may be inaccurate to



combine these studies to provide an estimated effect size. The lack of clear description of the intervention contents rendered it difficult to be sure that the interventions falling under the CBT umbrella were in fact similar enough to be grouped together. For example, some included imagery rescripting, to directly address the traumatic memory and its processing, whereas others appeared to focus more on working with the appraisals of the traumatic event, in a more standard CBT manner. These different intervention foci target different trauma maintaining processes and it may be an oversimplification to group these together and further research should seek to understand whether a different focus would lead to different effectiveness.

The standard CBT studies often had a wait-list control group whereas all NET studies used an active treatment, therefore limiting conclusions regarding the comparative effectiveness. The comparison of standard CBT to wait-list control may show that CBT is better than nothing in these situations, however further research is required to explore whether CBT is of greater benefit than supportive counselling or informal group support interventions. Comparing standard CBT to NET is somewhat inaccurate given this difference in comparison group and may well overestimate the effectiveness of standard CBT.

The meta-analysis used a random effects model, as advised by methodological literature owing to the differences in study samples and variations in the application of interventions (Borenstein, Hedges, Higgins, & Rothstein, 2010; Higgins & Green, 2008). The benefit of this random effects approach is that the statistical estimation of the effect size includes not only a consideration of within-study error but also between-study variation, which is not represented in the alternative fixed effect model. This is a more accurate representation in the current case, given the variation between studies. The random effects model however has the down-side of increasing the confidence-interval and reducing difference in the degree to which studies are weighted based on sample size, which makes results more uncertain and less sensitive to the impact of studies with larger sample owing to a different calculation of study weighting. Herein, the advantages of the random effects model, specifically that this reflects on estimate of the distribution of the effect of CBT on PTSD symptoms across a diverse set of samples and intervention applications, were chosen over the cost of less precision in estimated effect size.

## **Conclusions**

The identified research highlights general support for both the CBT model and the effectiveness of CBT based interventions. NET interventions are not currently supported as effective. CBT and general counselling interventions were common. Cultural adaptations typically included addition of locally relevant content such as games and delivery relying less on written information. The number of intervention studies identified was small for such a vast region and limitations in the

research revealed. However, criticisms of the studies must take into account the very real challenges of receiving funding and conducting research in this area. Overall there is insufficient evidence that explored the model or interventions to reach firm conclusions.

The danger of this review is the potential homogenising of sub-Saharan Africa, in terms of the culture, resources and burden of PTSD. It is vital to note that the vast region is composed of diverse cultures, within and between nations. This review highlights a lack of research on PTSD in the region and a lack of attempts to test the model. Research to assess the cultural appropriateness of the model, refine interventions and explore their effectiveness should be repeated across the region's diverse areas.

Within the resource-limited settings of many of the sub-Saharan African contexts and IDP camps, there is a real need to conduct effective and optimised interventions. Brief, lay-delivered interventions may suit these constraints. However research design and evaluation of these interventions should aim to meet the best practice standards demanded by funding bodies and service commissioners in more highly resourced countries.

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**Doctorate in Clinical Psychology, University of Bath**

**Service Improvement Project: Exploring Service User Engagement in Early  
Intervention for Psychosis Services: Barriers, Facilitators and Relevance of “Illness  
Perceptions”**

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### **Abstract**

**Objectives:** This study aimed to explore perceived barriers and facilitators to engagement with early intervention for psychosis (EI) services and to investigate the perceived relevance to service users and staff of illness perceptions as a way of improving engagement.

**Design:** Qualitative study with semi-structured interviews.

**Methods:** EI staff (six participants), service users (four) and family members of service users (six) were recruited from an EI service in Gloucester. A brief interview schedule was used which asked about barriers, facilitators to engagement, attitudes to illness perceptions as relevant to engagement and suggestions for interventions based on illness perceptions to improve engagement. Key points were transcribed. Data were analysed using Framework analysis.

**Results:** Barriers and facilitators to engagement were perceived at a range of levels, from wider social issues through health-care management and service design, to staff behaviours and service user perceptions. Illness perceptions were seen as relevant by all. A range of formats were seen as necessary to support engagement across different service users. Practical activities to show service users how EI can be useful and sharing service user experiences were seen as particularly helpful to support engagement.

**Conclusions:** Intervention focusing on assessing and adapting illness perceptions is relevant and potentially acceptable to service users, families of service users and staff. Suggested interventions now require further development and evaluation.

### **Practitioner Points**

- Perceptions about psychosis (what it is, consequences and control in particular) should be discussed with service users to assess if they are impacting on engagement.
- Information should be made available to service users about what psychosis is, its causes and consequences. Clear communication regarding what they and the service can do to help reduce distress may facilitate engagement.
- Practice should be developed to design and trial interventions to address illness perceptions. Staff could be prompted to ask about these perceptions. A range of resources could be made available to address perceptions, including information and previous service-user stories that explore the illness perceptions known to be more helpful to promote engagement.

## **Introduction**

Duration of untreated psychosis is associated with poor outcome including suicide risk, illness severity and experience of negative symptoms (McGorry, Killackey, & Yung, 2008). For people with psychosis improving engagement with services and treatment is a priority (Power, Harper, & Bullinger, 1999). Early Intervention (EI) services have been designed to attempt to identify and engage people with psychosis in treatment (Marshall et al., 2005). EI staff experience challenges with engaging people with EI itself. Indeed, rates of disengagement from EI services range from 18% to 25% (Conus et al., 2010).

Facilitators and barriers to engagement in EI services must be taken into account to inform practice. There are a number of static factors that predict engagement, such as history of abuse or age of onset of mental health difficulties (Stowkowy, Addington, Liu, Hollowell, & Addington, 2012). Previous research has identified areas for service improvement. Inflexible service rules, unfriendly staff, lack of communication and negative inpatient experiences were all associated with non-engagement (Stewart, 2013). Substance use is known to preclude engagement (Conus et al., 2010). Practical constraints around attending appointments and fear of the mental health system also limit engagement (Kreyenbuhl, Nossel, & Dixon, 2009).

Facilitators to engagement include good relationship and rapport with staff and access to peer support, which can both reduce isolation and negative beliefs about illness (Stewart, 2013). Engagement has been found to be supported by assertive case management (Baumann et al., 2013), the opportunity to talk about one's experiences (Byrne & Morrison, 2013), relationship with therapist (Lecomte et al., 2008), flexible approach with individualised interventions and therapeutic optimism (Ouellet-Plamondorr & Abdel-Baki, 2011). Age appropriate approaches that support the development of personal control are important to engage and retain service users (Green, Wisdom, Wolfe, & Firemark, 2012). Family involvement in care can benefit engagement (Kreyenbuhl et al., 2009).

A review of findings about service user preferences revealed the importance of help with practical issues, social and everyday activities, greater control and coping, independence and self-confidence, understanding of psychosis, individualised support and access to stories of others with psychosis (Byrne, Davies, & Morrison, 2010). Research suggests that including service users in the delivery of support may lead to improved outcomes and relates to service user preferences (Byrne et al., 2010; Lawn et al., 2007). The limited research exploring intervention preferences illustrates themes that may be relevant to engagement, as engagement may be increased if services address preferences.

Mental health staff may not receive any special training in engagement nor conduct any interventions specifically designed to increase engagement. A significant amount of mental health practice is based on “tacit knowledge”, which refers to implicit knowledge based on personal experience and may not reach awareness, rather one may act on instinct (Welsh & Lyons, 2001). This tacit knowledge does not always lead to effective interventions and it is necessary to shift to evidence-based practice (Enguidanos & Jamison, 2006). However, tacit knowledge may link to theory on which to build evidence-based practice. Exploring clinicians’ perceptions of barriers and facilitators to engagement and their current practice may elucidate such areas of tacit knowledge.

Psychological theory provides potential areas for focus to improve engagement. “Illness perceptions” in psychosis are associated with engagement with treatment (Williams & Steer, 2011). The term “illness perceptions” derives from health psychology theory (having been applied to various physical “illnesses”)<sup>1</sup>. Illness perceptions form part of the “common sense model” of illness and usually cover five dimensions: “identity” of illness (ideas about the identity of the condition, what is happening, what symptoms are linked to the illness, what the illness is called), cause, consequences, controllability and timeline, i.e. chronic or acute illness (Leventhal, Weinman, Leventhal, & Phillips, 2008). Williams and Steer’s (2011) cross-sectional study showed that perceived consequences (fewer), personal control (higher), treatment control (higher) and identity of illness (more coherent) were associated with (higher) self-reported engagement in treatment from mental health services.

A recent study exploring engagement with cognitive-behavioural therapy for people with psychosis reported that illness perceptions predicted engagement, regardless of severity of symptoms or insight into experiences (Freeman et al., 2013). The authors recommended that early work within CBT should focus on such perceptions of timeline and control. Furthermore, illness perception theory has been used to design a healthy living intervention for people with early psychosis (Bradshaw et al., 2012), based on the importance of assessing a person’s own view of their health to enable tailoring of information and promote engagement. This intervention is currently undergoing evaluation and is focused on health behaviour change. These illness perception concepts may be of use to directly addressing engagement with EI services.

Interventions in health psychology have addressed illness perceptions to increase attendance and adherence. For example, attendance at cardiac rehabilitation appointments has been improved by

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<sup>1</sup> The term “illness perception” is used throughout this study, however this is due to the origins of the theory from physical health, rather than meaning to imply psychosis as an “illness” necessarily. It would not be suggested that the term “illness perceptions” would be presented to service users.

eliciting the content of illness perceptions, exploring these with patients, providing education to correct inaccurate beliefs, and using cognitive techniques to draw out links between perceptions and behaviours to plan behaviour change (Broadbent, Ellis, Thomas, Gamble, & Petrie, 2009). Illness perceptions, particularly of control, consequences and understanding the identity of one's illness, may be readily addressed by CBT interventions (Watson et al., 2006). Exploring how staff think about illness perceptions in relation to engagement and how staff currently address engagement may highlight tacit use of illness perception theory. Identifying a relevant, potentially acceptable intervention to address these types of beliefs may provide a theoretically informed way to improve engagement for service users with EI services.

This service project aimed to address the following questions:

- 1) What do EI staff and service users see as barriers and facilitators to engagement with EI services? What do they currently do to facilitate engagement?
- 2) Does information from research findings associating "illness perceptions" with engagement have relevance for EI staff and service users?
- 3) How could a short intervention be delivered (face-to-face / telephone) aiming to improve engagement?

## **Methods**

### **Participants**

Three categories of participants were recruited. Present EI staff were recruited, with sampling reflecting a range of staff roles and professional backgrounds. The sample comprised a support worker, an activity co-ordinator, two social workers and two care co-ordinators / managers (Mental Health Nurses by background). Staff had been with the team between one and ten years. Family members or carers of previous EI service users were recruited through a local charity. Six parents of service users (two male) provided data during a focus group. Four people with personal experience of using the EI service were also interviewed (one male). All had been using the service for at least 12 months and were not in current crisis. Staff, carers and service users were not dyads or aligned to one another in any way.

### **Data collection tools**

An interview schedule was designed that asked about main facilitators and barriers to engagement. Staff were asked about their current practice to improve engagement and views of what worked well or less well. Carers and service users were asked to describe what steps staff had taken with them that had worked well or less well. The link was described between engagement and

perceptions of consequences of psychosis, person control and treatment control of psychosis and the “identity” of what was happening to them (for example, what the experiences are, what it may be called, what symptoms it has). All participants were asked to comment on links between engagement and these perceptions, if they felt these ideas could be addressed in intervention and how that could be done.

### **Procedure**

Informed consent was gained from all participants. Written information about the study was provided to all participants before arranging data collection. Staff were interviewed individually, except the social workers who were interviewed together for practical reasons. Service users were interviewed individually either via telephone or face to face. Carers took part in a structured focus group discussion. Where possible, interviews were audio recorded. When this was not possible (owing to problems with technology when attempting to record telephone interviews), extensive notes were taken during interview and checked with the participant during interview. Audio-recorded data were not transcribed in full, rather content was listened to repeatedly with participant responses transcribed in relation to the main topic question, i.e. facilitator, barrier, relating to illness perceptions (Clausen, 2012).

### **Analysis**

Framework analysis was used (Gale, Heath, Cameron, Rashid, & Redwood, 2013; Ritchie & Spencer, 1994). This approach is well suited to applied health research where specific questions are asked and the focus of analysis is on identifying actionable results (Ritchie & Spencer, 1994). In accordance with methodological guidance, the data were read and re-read. Data were coded. Codes for the barriers and facilitators more generally were derived from the data, however the general frame of barriers and facilitators was previously specified as per the aims of the project. Codes for illness perception types were specified *a priori*. All data were classified into a code and as either barrier or facilitator to engagement. The resulting framework was then refined, with some codes grouped together or deleted. A full framework containing all data was created. Interpretation of data focused on drawing out practical lessons with regards to factors to keep in mind around facilitators and barriers to engagement and analysis that leads to practical recommendations around potential intervention based on illness perceptions to improve engagement.

### **Results**

The coding framework is shown in Table 1, which illustrates the level (social, service, staff, family, individual, individual perception and then practice related issues), the name of the code, a brief description and the types of participants each code was mentioned by. Each code could include

barriers and/or facilitators to engagement. It is important to note that there were no specific discrepancies in the discussion of barriers and facilitators between types of participants. There were some codes that were mentioned by staff but not service users, for example. These generally appear to consist of topics that may simply be less evident for the different stakeholders. For example, issues around management may be less obvious to service users.

**Table 1 Analytic Framework and Description of Codes**

Level	Code	Description	Types of participants mentioned by
Social	Stigma	Perceived stigma of having a mental health problem, including self-stigma.	All
Service	Hospitalisation	The impact of hospitalisation on elements of engagement, beliefs about services and beliefs about mental health	Staff, service user
Service	Resources	Venue, cash, transport and pressures on time	Staff, carers
Service	Staff management	Caseload and staff pressure, training, varied types of staff	Staff, service users
Service	Other management	Information management (including with family) and sharing, dealing with “Do not attends”.	Staff, carers
Staff	Characteristics	Elements of staff approach and personal characteristics that were associated with engagement, such as respect and friendliness.	All
Staff	Arrangements	How staff arranged appointments with respect to where, when, mode of contact	All
Staff	Flexibility	Flexible approach explicitly referred to, may cover material about making arrangements and also overlap with person centred approach, however comments where flexibility is directly mentioned.	All
Staff	Relationship	Building relationship with clients / “service users”— how done and the impact of this on clients to be able to feel comfortable.	All
Staff	Showing usefulness	Stories of importance of showing clients the practical use that the staff can be to them.	All
Staff	Person centred	Individualised approach used by staff where the person’s goals are focused on and client sets priority.	Staff, service users
Family	Family	Family members as providers of support and requiring support also.	All (however fewer service user comments)
Individual	Lifestyle	Lifestyle of clients including substance use.	All (however fewer service user comments)
Individual	Worries	Anxiety in the life of the client, including anxiety arising from psychosis as well as pre-existing anxiety.	Staff, one service user

Level	Code	Description	Types of participants mentioned by
Individual	Reject illness	Ideas about having psychosis are rejected or it is hidden away.	Service user, carers and one staff member
Perception	Identity	Ideas about the identity of the condition, knowing what is happening to you and having a coherent idea about this.	Service user, staff
Perception	Cause	Beliefs about what has caused the difficulties.	Service user, staff
Perception	Consequences	Beliefs about what will happen because of psychosis (not including beliefs about what treatment will entail)	All
Perception	Timeline	Ideas about how long difficulties will remain.	One service user
Perception	Personal control	Beliefs about what the individual can do themselves to help control the impact of psychosis.	Staff, service users
Perception	Treatment control	Beliefs about what treatment can do to help control psychosis, with treatment including the EI team generally as well as medication more specifically.	All
Perception	Treatment concerns	Worries, concerns and negative experiences of treatment.	All
Perception	Treatment necessity	Ideas about the degree to which treatment is needed.	All (one service user)
Practice	Groups	Use of group interventions, including using peer group.	Staff, service user
Practice	Motivation	Factors associated to motivation and use of techniques such as motivational interviewing.	Staff, carers
Practice	Activity	Involving clients in activity.	All
Practice	Tailored	Current practice and ideas about the importance of tailoring intervention to the individual in terms of preferences and life priorities. Overlaps with person centred to some degree, however person centred may include ethos and general ideas about person's priorities, whereas here the focus is more on what and how to tailor.	All
Practice	Normalising	Examples of normalising mental health difficulties.	Staff, service user
Practice	Practical	Interventions that relate to solving practical difficulties.	Staff
Practice	Formats	Range of formats of mode of delivery of interventions.	All

A detailed tabulated presentation of the results is provided in the Appendix 2 for further information. Findings are summarised here for each code.

### *Social level*

Participants described stigma as providing a general barrier to access to services. Staff described working without reference to diagnosis in order to avoid stigma, sometimes avoiding naming the

experience because “I think the word psychosis, whilst it’s still better than schizophrenia, I think it still carries quite a bit of stigma”.

### *Service level*

Hospitalisation was associated with fear and unpleasantness, which in turn led to a barrier to engaging with EI owing to concerns of having to return to hospital. For example, “I was frightened of being sectioned so eventually I wouldn’t go to the appointments...because I feared they would do it” (service user).

EI resources and management were also discussed. Resources were limited and seen only as barriers. The service’s premises were seen as providing a poor environment. A lack of petty cash limited activities staff could do with service users. Management issues were both barriers and facilitators. The multi-disciplinary team and its flexibility helped engagement, whereas lack of training in engagement and increasing caseloads were barriers. The open referral systems and information sharing via “Rio” electronic records system facilitate engagement, however the challenge of using that information and sharing it with others appropriately (particularly with parents) were barriers. A family member / carer stated “as a parent you are morally responsible but not privy to the information”.

The service provides staff with a great deal of information, which was sometimes overwhelming. However, engagement was no longer part of staff training or development: “We used to have this course, it was useful to learn about and think about validation of emotions, things like that” (staff) and “We don’t do any specific training on engagement, you either just pick it up or you do it already” (staff).

### *Staff*

Talk of staff highlighted facilitators to engagement. Characteristics of staff were “charismatic”, “warm and friendly”, “helpful” and showing good interpersonal skills. A service user commented “The staff, they are great people, with great people skills; they spoke to you like a human being”.

Staff practices around making arrangements with service users were identified as relevant. An assertive approach was useful, with regular contact and prompting. Routine and creation of stability were important for some to remain engaged. Venue for meeting was important, with attempts to normalise and meet at a place that is “socially inclusive” (staff). A flexible approach to making arrangements, timings, location and doing “normal” things with clients were all advantageous to engagement.



Building relationships with clients was seen as highly important to improve engagement, with staff using appropriate language and empathy skills. A service user commented that “seeing the same person, building that relationship and knowing that was going to happen” helped them to engage. Staff talked about trying to maintain a sense of what using EI services is like for people and to use that sense to behave empathically to promote engagement. Service users seemed to notice this, “they are like trying to understand you...you get the impression that they know, know where you are coming from”.

Demonstrating the usefulness of the service was key to improving engagement, with staff focusing on what they can do for a service user to show how the service can help in a concrete manner. One service user talked of how staff appeared to be “fighting along with me, in my corner, to help me...so there was a point to it, to seeing them”.

Together these codes relate to the person-centred approach. Staff were focused on meeting individual’s needs, “it’s not necessarily looking at what’s the diagnosis but what it is they are struggling with, what is it that they want help with” (staff).

### *Family*

Supporting parents and providing them with information was seen as useful for engagement, as family often have ongoing contact with service users. Family were able to encourage people to engage. Staff described how “it helps to support parents so that they know about psychosis and can offer support the other 23 hours of the day when we are not there”. Family were asking for more involvement, saying “use the family; they have the most knowledge about the person who is unwell”. No details were provided about how staff worked with family / carers to help with engagement.

### *Individual*

Lifestyle, particularly alcohol and substance use, could be a barrier to engagement as this could lead to missed appointments and difficulty making contact. Anxiety and lack of trust, sometimes owing to the nature of the mental health difficulties, also reduced engagement. A service user described worrying what EI staff “really wanted to know from me” and therefore finding it hard to engage owing to this suspiciousness. Rejection of the idea of being unwell or needing help also reduced engagement. Family described experience with a service user as “very private, hide everything...he did not want to admit he was unwell”. Those who felt there was nothing wrong were understandably unlikely to engage, as there was no perceived need.

### *(Illness) Perceptions*

Relating to rejection of the idea of being unwell, participants described how an understanding of what is happening (“illness identity”) was needed for engagement, with information about psychosis helping. A member of staff described how “you are going to have to talk a little bit about psychosis and sort of check out their understanding”. Another staff member described trying to “explain as fully as we can what psychosis is...what that actually means and kind of break that down”. Service users described it was useful to engagement when “they helped me understand what I was going through”. Language regarding the identity of illness was cautious, with concerns around “what they associate with the word” (staff). Service users on the other hand seemed keen to have a clear, “simple discussion, simply drawing attention to information in a way that was relevant” and feeling that a “definition of psychosis and list of things people may do and how I fitted that” could help engagement.

Seeking a cause for the distress and discussing this was mentioned as useful to engagement also. Perceived consequences were also discussed. Staff and service users emphasised the importance of optimism about recovery. For example, staff talked about “maintaining hope...light at the end of the tunnel”, whilst a service user found the following useful to help them engage “they [EI staff] said it would be ok, clearly said it would be ok, had some hope”. This relates to the perceived timeline of psychosis also. A service user described how when “I didn’t think it would go away, that’s it forever” he was unable to engage with services.

Perceptions around control were seen in relation to both personal control and treatment control. Showcasing and encouraging the personal control service users can have over their mental health were beneficial to engagement. Staff worked on “empowering someone to take control of their life”. Similarly, service users found action planning approaches helped them engage and feel hopeful: “We talked about what we could do to help”. Beliefs in the control of treatment (broadly construed and going beyond medication alone) were also beneficial to engagement. Family members talked about how treatment assisted people to leave hospital, and this in itself gives people a sense of control. Service users described how knowing that EI “can be really successful treatment” facilitated engagement. Fewer worries about treatment and greater belief in its necessity also helped. Lack of consideration of side effects and negative first experiences with EI raised concerns for service users about using EI. Staff worked on building beliefs about treatment necessity and effectiveness, “Trying to help people understand how attending and engaging in activities will perhaps help them”.

### *Practice*

Groups and peer support were highly valued as facilitating engagement. Activity groups are currently run, however extensions to this were suggested. Currently staff facilitate groups. The options of more informal groups to meet other service users and “having another person who’d been ill and hear about that” (service user) were raised.

Motivational interviewing was found useful by staff and family members remarked on how engagement depends on working with motivation. Activities were a way to generate motivation to use EI services. Being engaged in practical or leisure activities promoted confidence, supported the usefulness of the service and helped engagement.

Tailoring of intervention was essential, supporting further the importance of person-centred, flexible approaches. Normalising and practical intervention helped service users engage. Staff described it was important to “talk about normal real life stuff”. This also was thought to reduce alienation and social isolation.

Formats for intervention delivery were suggested, with a range of approaches suggested including fact sheets about psychosis, structured workbooks around perceptions and questions for staff to hold in mind. Service user stories and mentoring were strongly felt to be novel approaches to facilitate engagement, for example “Perhaps giving some examples of people who are living with the diagnosis and are successful and or even example, obviously anonymous, of people from our own practice...who have gone on to finish their degree or that kind of message” (staff).

## **Discussion**

Barriers and facilitators to engagement were highlighted across a range of levels, from wider social levels down to individual perceptions. The dimensions of the illness perceptions were thought to be relevant by participants. A range of potential intervention topics and formats were also elicited.

### **Barriers and facilitators to engagement**

Although “illness perceptions” had relevance, this was just part of engagement. Barriers and facilitators to engagement with EI highlighted the ongoing impact of stigma and fears of hospitalisation. Service factors concerned the support of staff to maintain their flexible approach to working with clients, including case-load management and flexible approach to making appointments. Staff characteristics facilitated engagement and interpersonal skills were important. Results suggest that staff recruitment and supervision to prioritise and maintain such skills may be

beneficial. The good practice around relationship building, person-centred care and normalising is also highly relevant. Additionally, the concept of “showing the usefulness” of EI services to the client appeared crucial and this relates to ideas about treatment control and necessity.

The barriers and facilitators to engagement elicited here draw together issues highlighted in previous research. These include staff communication issues and negative illness beliefs (Stewart, 2013); service user substance abuse (Conus et al., 2010); the practical challenges of making appointments, unpleasant previous experiences with the health services and family involvement (Kreyenbuhl et al., 2009); the opportunity to talk and have a good relationship with a therapist (Byrne & Morrison, 2013; Lecomte et al., 2008); an individualised approach as central (Ouellet-Plamondorr & Abdel-Baki, 2011); and engagement in activities, greater control, a good understanding of psychosis and a collaborative approach (Byrne et al., 2010). Furthermore, previous research has suggested that service users should be included in delivery of interventions, which may improve engagement (Byrne et al., 2010; Lawn et al., 2007).

### **Illness perceptions**

Extending prior research, this study also explored illness perceptions. Illness perceptions were seen as having some relevance by all participants. Information needs around what psychosis *is* were evidenced. Causal perceptions were also important. Staff discussed needing a way to talk about causality. Consequences of psychosis were discussed, with a need to communicate that these are not necessarily severely impacting life in an ongoing way. This linked to perception of the timeline as being forever, which impacts negatively on engagement. Personal control perceptions were seen as relevant to engagement. Engagement was seen as reduced by beliefs around medication as dangerous or treatment as unnecessary as it was unclear how it could help. Clear communication around these issues is required, with examples of what people can do for themselves, what the service offers and how this can be successful.

Our findings support the quantitative study showing the association of types of illness perception with engagement (Williams & Steer, 2011). Our findings related not only to “illness perception” theory, but also to ideas similar to those found in research looking at “Beliefs about medication”, giving rise to the Necessity-Concerns Framework (Horne, Weinman, & Hankins, 1999). Here, beliefs about treatment (broadly construed) *necessity* and *concerns* about potential negative consequences of treatment were discussed. Staff workshop could consider how to balance *necessity* and *concern* beliefs specifically around engaging with EI services.

Staff revealed how illness perceptions were implicitly part of current practice for some. Staff talked particularly about doing activities to show that the service can be of benefit, addressing “treatment”

control. Staff were using information leaflets about psychosis occasionally, at other times finding it difficult to know how to discuss psychosis although they were aware that this was important for engagement. The tacit knowledge seen amongst staff may provide a useful basis for further training to develop practice based on illness perceptions theory.

### **Implications for practice**

Implications for service practice arise from these data. It was clear that a range of approaches would be required, mirroring the individualised approach that is at the core of EI (Shiers & Smith, 2010). Staff training on ways to improve engagement appears indicated, to share elements of practice that facilitate engagement. Furthermore, staff training could more specifically focus on illness perceptions to help staff explore how to raise the issues, assess the beliefs, engage in discussion to foster change and develop more helpful perceptions, that support engagement. Short-format reminders of the core issues and questions could be made available, for example a credit-card sized list of relevant questions to keep in mind. Staff could therefore integrate these questions and concepts into their existing practice. Other formats such as the use of the “Illness perception questionnaire” for schizophrenia (Lobban, Barrowclough, & Jones, 2005) could be made available and this more structured approach to raising the issues for discussion may suit some individual clients.

Family may have more frequent contact with the clients and are often the people who first approach services to try to engage the client (Singh & Grange, 2006). Family or carers could be involved to support engagement by asking questions around illness perceptions or delivering messages that are associated with better engagement. This could be achieved through a brief workshop with family or information sheet covering the types of perceptions that are relevant and brief statements, similar to that suggested for staff.

The provision of an intervention to clients was also suggested by the participants. A structured workbook was suggested by one participant to help guide clients through the perceptions and support development of perceptions that may facilitate engagement. Short, easy read fact-sheets can provide information about “illness” identity, consequences, personal control and treatment control, in addition to activities around each set of beliefs to help stimulate discussion and any cognitive change.

The use of stories from previous service users was felt by many to be potentially useful. Peer support groups have been found useful for treatment of psychosis (Castelein et al., 2008), however it may be that using peer support at the start of a person’s relationship with services may benefit engagement. There is also the possibility of adapting the “Expert Patient” model which

encompasses the use of people with personal experience in delivering interventions and supporting others (for example Lorig et al., 2008). A pilot Expert Patient Programme group intervention (with one-to-one work with a health care provider) was found to improve sense of control of psychosis and decreased hospitalisation (Lawn et al., 2007). The service users reported value in sharing similar experiences with others. Development of using this type of intervention including people with a range of serious psychiatric difficulties remains novel and is ongoing, with promising results (Crepaz-Keay & Cyhlarova, 2012; Lorig, Ritter, Pifer, & Werner, 2014). An adaptation whereby a previous service user provides highly structured, brief discussion session around relevant illness perceptions could be trialled. It was clear from the data that co-delivery of intervention by people with personal experience may be beneficial, not least as they can have additional credibility for current service users and can serve as role models. This is not part of current practice and could be developed.

This study has several limitations. The sample size is small and recruitment took place through service managers and staff, potentially biasing the responses. Additionally, only service users who had engaged were interviewed, limiting knowledge around barriers to engagement. Only recommendations for interventions arise from the data. Further work should develop intervention examples from the recommendations. For example, short prompts for staff to raise the issue of perceptions with clients could be developed. A credit-card sized prompt could be given to staff, who would be asked to use them with new referrals. After six months, this could be evaluated qualitatively as to the degree to which staff used the questions, how comfortable they felt discussing these issues, perceived impact of client engagement and suggestions for improvement. The implications for service improvement were shared with the service and stakeholders. Engagement is seen as one of several priorities for the service in its development. The service intends to discuss the recommendations and together select from the recommendations to develop illness perception based intervention for use in their practice. Information and staff training for how to assess illness perceptions and provide relevant information is felt to be the most likely first step.

In conclusion, the concept of illness perceptions was perceived as a relevant element of engagement in EI services. Participants' responses indicated the ideas were acceptable and made suggestions for interventions to promote discussion and change of illness perceptions. These included staff and family member training on the relevance of illness perceptions and how to elicit and work on these, improvements to patient information and the potential role for peer-mentoring. Further work is now needed to develop, trial, evaluate and improve intervention.

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Doctorate in Clinical Psychology, University of Bath

**Main Research Paper: An Experimental Test of “Somatisation” in People with  
“Medically Unexplained Symptoms”**

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### **Abstract**

**Objective:** Somatisation as a process suggests that mood changes are responded to physically rather than psychologically. This concept is linked to “medically unexplained symptoms”, including conditions such as chronic fatigue or fibromyalgia. Alexithymia, difficulty in identifying or expressing emotions, is the proposed causal mechanism. This study tested this proposal by measuring association between alexithymia and somatic symptoms and exploring whether experimentally induced mood changes are responded to by those with higher alexithymia scores with more physical than psychological sensations than those with lower alexithymia.

**Methods:** A median split of Toronto Alexithymia Scale scores was used to create two groups (higher and lower alexithymia) from a sample of 21 participants with a diagnosis of chronic fatigue syndrome and / or fibromyalgia. Participants rated mood and physical and psychological state at baseline and following sad and happy mood induction. Ratio scores of psychological over physical state ratings were calculated for each mood state. Measures of depression, anxiety, somatic complaints, acceptance, beliefs about emotions and health anxiety were also administered.

**Results:** No correlation was found between alexithymia and intensity of somatic or psychological symptoms. There was no significant difference in ratio scores by mood or between those with higher or lower alexithymia. The mood manipulation did lead to changes in psychological sensations and physical sensations.

**Conclusion:** The alexithymia hypothesis of medically unexplained symptoms was not supported in this study using a clinical sample. Further research should include a control group of people experiencing depression or anxiety without significant physical symptoms.

## Introduction

Somatisation is a widely used term, which has come to mean both a disorder and a process. As a process, it is said to be the physical expression of psychological distress. (Bridges & Goldberg, 1985). It has been influenced by the psychoanalytic tradition and become incorporated into folk psychology, and has become associated more recently with “medically unexplained symptoms” (De Gucht & Fischler, 2002).

“Medically unexplained symptoms” (MUS) is the term used by some to refer to a range of symptoms for which there is no known pathophysiology or defined medical cause. The term encompasses a range of conditions such as Chronic Fatigue Syndrome (CFS), Fibromyalgia and forms of rheumatism and intestinal difficulties such as irritable bowel syndrome (IBS) (Paukert et al., 2010). MUS conditions are commonly seen in general practice (Bass, Peveler, & House, 2001), appearing in 16% of patients (De Waal, Arnold, Eekhof, & Van Hemert, 2004). MUS are commonly found to be related to experience of depression and anxiety (Paukert et al., 2010). MUS cause disability, increased use of health services and significant cost to the economy (Konnopka et al., 2012).

MUS was intended to be theoretically neutral (Mayou, 1993). Despite this, the concept of MUS has become controversial (Rief & Isaac, 2007; Starcevic, 2006; Stone et al., 2002). The term is used somewhat inconsistently and is problematic to define. MUS conceptually overlaps with the idea of “somatisation” (Lipowski, 1988, p. 1359). In psychoanalytic and psychodynamic approaches, MUS has become a proxy term for somatisation, having been defined for example as “the use of the body to express psychological states” (Gabbard, Litowitz, & Williams, 2012, p. 584). This idea remains influential in research literature and is evident in practice. In a survey of GPs understanding of MUS, over 63% felt patients with MUS have a psychiatric disorder and “psychological problems were thought to be a major contributor to MUS” (Reid, Whooley, Crayford, & Hotopf, 2001, p. 521). There are a number of other theories regarding the relationship between MUS and experience and/or expression of emotion, including findings around differential help-seeking, degree of health risk behaviours and over-focussing of attention on bodily sensations (Baiardini, Abbà, Ballauri, Vuillermoz, & Braido, 2011; Barsky, 1992; Deary, Chalder, & Sharpe, 2007). A causal relationship between unexpressed psychological distress and somatic symptom experience has been suggested (De Gucht & Fischler, 2002).

The concept of “alexithymia” was developed through review of characteristics of twenty people with “classic psychosomatic disease”, meaning ulcers, arthritis, ulcerative colitis, asthma and

eczema (Nemiah & Sifneos, 1970). However several of these “psychosomatic” conditions are now linked to known medical causes. Alexithymia was more clearly defined as measures were developed. Alexithymia refers to difficulty identifying feelings, describing feelings to others and externally oriented thinking (Bagby, Parker, & Taylor, 1994a; Bagby, Taylor, & Parker, 1994b).

Alexithymia is the psychological mechanism proposed to be causal in MUS (for example Smith, Conway, & Cole, 2009; Taylor, 1984). The proposed relationship between alexithymia and MUS is that those who find it difficult to recognise or express emotions tend instead to experience physical symptoms and therefore “somatise” their distress. The stress alexithymia hypothesis suggests that in the presence of stress that would normally evoke an emotional response, the person who is high in alexithymia does not experience an emotional response, rather they experience somatic symptoms (Martin & Pihl, 1985). Such explanations of somatisation / MUS as linked to alexithymia remain commonly mentioned in the literature (for example Nyklíček, Vingerhoets, & Zeelengberg, 2011).

The manner in which alexithymia “causes” MUS is not clearly elucidated in the research literature. Some suggest that alexithymia is a defence mechanism. In his popular book, the medical doctor Sarno suggests that mood states, such as depression, and physical symptoms of MUS are all generated from the same cause – an underlying psychological difficulty or conflict, with alexithymia suggested by some as being the defence against the psychological difficulty (Sarno, 2010). As such, here mood, alexithymia and MUS are linked, with the alexithymic defence acting as a precipitant of the MUS. Alexithymia then causes MUS as psychological distress is unprocessed. The mechanism by which the defence against emotion then causes MUS is not explained. Others suggest misinterpretation or misattribution of sensations as the causal mechanism. It has also been suggested that owing to “diminished ego capacity”, which may be manifest as alexithymia, that there is a perceptual error meaning psychological distress (anxiety or depression) is interpreted as bodily symptoms (Smith, Conway, & Cole, 2009). It is not clear by what precise mechanism this takes place, however it is implied that alexithymia means psychological distress is not understood and therefore an alternative explanation for the bodily symptoms that often accompany psychological distress is required. The link then extends beyond mere “stress” which implies anxiety, to a broader idea of “distress” which also implicates depression as a signal that can be misinterpreted and cause, through alexithymia, MUS.

The extent to which research supports this proposed relationship is unclear. The link between alexithymia and physical response to stress has been investigated. People higher in alexithymia have been shown to have greater physiological (heart rate and cortisol) responses to stress than people low in alexithymia (for example Timary, Roy, Luminet, Fillée, & Mikolajczak, 2008;

Rief, Hiller, & Margraf, 1998), although this has not been related to MUS. The relationship between MUS and alexithymia has mixed results. For example, Kooiman et al (2000) found no significant relationship between alexithymia and somatisation / medically unexplained symptoms. However, systematic review reports a small to moderate relationship between MUS and alexithymia (De Gucht & Heiser, 2003). The strength of this relationship suggests alexithymia may not be causal to MUS. Linking the three concepts together, the extent of a physical response (rather than psychological response) to stress in people with MUS as caused by alexithymia has not been tested. Reviewing studies of alexithymia and MUS, Kooiman (1998) points out the lack of clarity in the literature, partly due to the dominance of cross-sectional designs, a failure to take into account the differing levels of alexithymia observed within people who somatise and a tendency not to control for anxiety and depression, which relate to both alexithymia and presence of physical symptoms. More recently, Taylor and Bagby (2012) have reviewed the literature finding no experimental studies exploring the relationships between stress, alexithymia and somatic complaint.

There are other variables that may relate to MUS and affect. People experiencing MUS may have elevated depression and anxiety as a result of physical distress. Further, health anxiety may lead to increased monitoring and reporting of physical sensations (Storch et al., 2008; Wilson & Hall, 2012). Beliefs about emotions and acceptance of emotional experience may relate to alexithymia scores; alexithymia may relate to beliefs that emotions are unacceptable and these beliefs may affect symptom reporting (Wells, 1995; Wilson & Hall, 2012). It is important to explore the role of these variables in any relationship between alexithymia and MUS.

## **Hypotheses**

This study addresses a significant gap in the literature by presenting an experimental study to test the alexithymia hypothesis of MUS. There are two (one-tailed) hypotheses:

- 1) Addressing association in people with MUS between alexithymia and physical symptoms, the theory of somatisation suggests the hypothesis that alexithymia scores will correlate positively with experience of somatic complaint (as measured by the PHQ-15) and negatively with measures of adverse mood.
- 2) The theory would predict that in experimentally induced sad versus happy mood, those scoring high on alexithymia will show a greater decrease in the ratio of psychological to physical sensations when compared to those scoring low on alexithymia and when controlling for baseline anxiety and depression scores. Specifically, for people with MUS, at the sad mood point participants will report significantly more physical sensations than at other mood points, however not for psychological sensations.

## Method<sup>1</sup>

### Design

Relationships between TAS-20 and symptom reporting were examined cross-sectionally. A mixed model experimental design was also used. The within participants factor was the mood manipulation, with data collected at baseline, post sad mood induction and post happy mood induction. Repeated measures of the psychological and physical sensations were collected. The between participants factor was alexithymia score – participants were divided into two groups (higher TAS and lower TAS) using a median split based on their TAS-20 scores.

### Participants

Participants were recruited from specialist fibromyalgia and CFS services across Bath and Bristol and through a national fibromyalgia charity. Selection criteria were current diagnosis of fibromyalgia, CFS and / or IBS that were not due to treatment (e.g. post-cancer treatment fatigue). No cut-offs in terms of level of anxiety or depression were applied.

### Measures

The Toronto Alexithymia scale (TAS-20) was used to measure alexithymia and has been reported to be valid (three factor structure congruent with the alexithymia theory) and reliable (Cronbach's

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<sup>1</sup>As discussed further in the Connecting Narrative, the planned study design included two groups of participants: a group with MUS ("case" group) and a "control group" of people with anxiety or depression. This would have allowed comparison of psychological and physical responses to distress in people with primarily physical distress (MUS) and people with primarily psychological distress (control group). The "control" group was planned, to be drawn from participants with depression or mixed-anxiety-depression diagnoses, who do not have a serious or chronic physical health condition. Participants for the control group were recruited via primary care mental health services (Improving Access to Psychological Therapies) across Swindon and Gloucester, advertisements in local pharmacy and via local counselling services. Despite extensive attempts to recruit participants for the control group, this was not achieved. Data were collected from only three control group participants. As such, it was necessary to alter the research design using the MUS sample only. The hypotheses were applied to the MUS sample, comparing groups with higher and lower alexithymia, based on TAS-20 scores. The rest of the paper reflects this revised design. For information, the original power calculation was conducted on the basis of ANCOVA 2 (MUS / control group) by 2 (high / low alexithymia), and covarying for baseline anxiety and depression. Owing to the lack of experimental research in this area, estimation of sample sizes based on previous research is limited however Connelly and Denney (2007) report the effect of stress tasks on physical and psychological variables in relation to higher or lower alexithymia. The effect sizes achieved therein comparing pre-post stress range from  $d=0.86$  to  $0.42$ . Using G\*Power software to estimate required sample size with power 0.80, alpha 0.05, effect size estimated at 0.4, numerator df 1 (level within each independent variable – 1), number of groups entered as 6 (four groups from the 2x2 design plus two for the covariates) and 2 covariates, required total sample size is 52 (Faul, Erdfelder, Lang, & Buchner, 2007), 26 participants in MUS group and 26 participants in the control group).

alpha =0.81, test-retest reliability correlations 0.77,  $p<0.1$ ) (Bagby et al., 1994a; Bagby et al., 1994b). The scale scores range from 20 to 100, with scores over 60 indicating alexithymia (Taylor, Bagby, & Parker, 1997).

The Generalised Anxiety 7-item scale or “GAD-7” was used to measure anxiety, this measure has been shown to have good construct validity, excellent internal consistency (Cronbach’s alpha 0.92), good test-retest reliability (intraclass correlation 0.83) and is sensitive to detect anxiety compared to structured psychiatric interview (Spitzer, Kroenke, Williams, & Lowe, 2006).

The Patient Health Questionnaire 9 or “PHQ-9” was used to measure depression and this measure has been shown to have good construct validity when scores were compared to depression diagnostic status, excellent internal consistency (Cronbach’s alpha 0.89) and good test-retest reliability (intraclass correlation 0.84) (Kroenke, Spitzer, & Williams, 2001)

The Patient Health Questionnaire 15 or “PHQ-15” provided a measure level of somatic complaint, providing an indication of the experience of medically unexplained symptoms (Kroenke, Spitzer, & Williams, 2002). This measure has been shown to be sensitive to somatic symptoms when compared to other ratings of symptoms and functional status and has good internal reliability (Cronbach’s alpha 0.80 in the primary care sample) (Kroenke, Spitzer, & Williams, 2002).

The “Beliefs about Emotion Scale” or “BES” measured participants’ view of emotions and has been shown to have high internal consistency (Cronbach’s alpha 0.91) and to correlate as expected with related constructs of perfectionism, dysfunctional attitudes and depression (Rimes & Chalder, 2010).

The Acceptance and Action Questionnaire or “AAQ” was used to measure the acceptability of emotions (Bond et al., 2011). This measure has good internal consistency (mean Cronbach’s alpha across subscales of 0.84) and test-retest reliability (intraclass correlations 0.81 at 3 months) and validity is supported by comparisons with thought suppression (which correlated positively with psychological inflexibility at 0.63) and emotional distress (for example with depression scores at 0.71) (Bond et al, 2011).

The “Very Short Health Anxiety Index” or “VSHAI” was used to assess health anxiety. This brief questionnaire has validity and reliability comparable to longer versions of this questionnaire (Salkovskis, Rimes, Warwick, & Clark, 2002).

Visual analogue scales (VAS) assessing a) physical sensations and b) psychological distress were used as the main experimental measures. An item asked about current levels of depression, to check whether the mood manipulation was successful. The remaining eight items asked about level of psychological (sad, stressed, strong negative thoughts, worried) and physical sensations (physically uncomfortable, pain, headache, fatigue) and have been previously used in this format in related research (Hall, Kuzminskyte, Pedersen, Ørnbøl, & Fink, 2011). The maximum score for the manipulation check items is 100 and a maximum of 400 would indicate extreme psychological or physical sensations. (Measures are shown in Appendix 3).

### **Procedure**

Ethical approval for this study was gained from NHS National Research Ethics Service. Informed consent was gained from all participants. They completed the TAS-20, either prior to or at the data collection meeting. Participants then completed the baseline VAS, GAD-7, PHQ-9, PHQ-15, BES and VSHAI. Participants then completed the sad mood induction following by the VAS (“sad VAS”) and then a happy mood induction, repeating the VAS a third time (“happy VAS”).

Standardised instructions and stimuli were used in the mood inductions. For the sad mood induction, people were given the following information and listened to “Russia under the Mongolian Yoke” by Prokofiev, played at half speed for around five minutes.

“I would like you to try to get into a depressed mood. The music you will hear is designed to help you get into that sad mood. Please absorb yourself in the music and get into the mood suggested by the music. You can also think about sad images or memories.”

For the second mood induction, an excerpt of around five minutes of Coppelius” by Delibes was used to generate positive mood. The instruction was

“I would like you to try to get into a happy mood. The music you will hear is designed to help you get into that happy mood. Please absorb yourself in the music and get into the mood suggested by the music. You can also think about happy images or memories.”

These pieces of music were chosen based on previous research (Clark, 1983; Tang et al., 2008). Following positive mood induction, participants were thanked and debriefed.



## **Results**

### **Sample characteristics**

For the whole sample, 3 (14.3%) participants were male. All males were in the higher TAS group (25% male in higher TAS group). Age, scale scores for low mood, anxiety, somatic complaint, psychological acceptance, beliefs about emotions, health anxiety and baseline physical and physical sensations are given in Table 1. There were no significant differences between the higher and lower alexithymia groups on any variable other than the TAS-20. The median score for the whole sample was 49, therefore the “lower TAS” (n=9) scoring less than 49 and “higher TAS” (n=12) scoring 49 or more.

**Table 1 Sample characteristics for whole sample and high / low alexithymia groups**

Variable	Whole sample (n=21) mean (s.d.)	Higher TAS (n=12) mean (s.d.)	Lower TAS (n=9) mean (s.d.)	t-test (df=19) (p=0.0001)	Effect size (d)
TAS-20	47.7 (9.11)	54.2 (5.69)	39.0 (3.87)	6.874**	3.12
Age	47.5 (10.49)	46.2 (8.75)	49.2 (12.8)	0.651	0.27
PHQ-9	15.0 (4.36)	15.9 (4.62)	13.7 (3.87)	1.181	0.52
GAD-7	11.4 (4.78)	11.1 (5.87)	11.8 (3.07)	0.322	0.15
PHQ-15	15.6 (3.64)	15.9 (4.21)	15.1 (2.89)	0.492	0.22
AAQ-II	29.7 (6.60)	30.4 (8.30)	28.7 (3.50)	0.592	0.27
BES	45.2 (12.96)	47.8 (13.38)	41.8 (12.29)	1.047	0.47
VSHAI	9.9 (3.39)	10.3 (3.39)	9.3 (3.50)	0.659	0.29
Baseline psychological	151.9 (81.66)	166.6 (85.70)	132.3 (76.28)	0.949	0.42
Baseline physical	200.6 (75.50)	203.9 (71.85)	196.2 (84.34)	0.226	0.10

\*\* significant at  $p < 0.001$

### Analysis of cross-sectional data

#### *Relationship between alexithymia and sensation reporting*

Pearson's correlation found no significant relationships between alexithymia scores (TAS scores) and PHQ-15 "somatisation" scores, depression scores from PHQ-9, anxiety from GAD-7, health anxiety from VSHAI and baseline ratio of psychological to physical scores. These are detailed in Table 2, for completeness.

**Table 2 Correlations between alexithymia and sensation reporting**

	PHQ-15	PHQ-9	GAD-7	VSHAI	Baseline ratio
Pearson's r (p value)	-0.077 (0.740)	0.352 (0.118)	0.033 (0.887)	0.229 (0.318)	0.163 (0.480)

### Analysis of experimental data

#### *Manipulation check*

The depression item from the VAS was an estimate of the effect of the mood manipulation (possible range 0-100). Mean scores are shown in Table 3.

**Table 3 Mean mood manipulation check scores**

Mood	Whole sample - Mean (s.d.)	Higher TAS - Mean (s.d.)	Lower TAS - Mean (s.d.)
Baseline	38.1 (24.63)	43.5 (24.37)	31.0 (24.47)
Sad	47.3 (25.93)	48.1 (23.98)	46.2 (29.79)
Happy	25.48 (22.67)	27.7 (23.64)	22.6 (22.36)

A 3x2 mixed model, repeated measures ANOVA was conducted to compare depression rating at each mood (baseline, sad, happy) between TAS group (higher or lower). No effect of group was found ( $F(1,19) = 0.545$ ,  $p=0.469$ ). The main effect of mood was significant ( $F(2,19) = 7.791$ ,  $p=0.005$ , partial  $\eta^2 0.582$ ). The interaction was not significant ( $F(2,19) = 0.570$ ,  $p=0.575$ ). As there was no effect of group, paired t-test comparisons using the whole sample data were conducted to check manipulation effect. Comparing baseline to sad, there was no significant difference ( $t(20) = 1.359$ ,  $p=0.189$ ). Comparing sad to happy revealed significant change in the depression rating ( $t(20) = 3.832$ ,  $p=0.001$ ).

### ***Reporting of psychological and physical sensations***

Psychological and physical sensation VAS scores from baseline, post-sad mood induction and post-happy mood induction are given in Table 4, the ratio of psychological to physical sensations is also shown.

**Table 4 Psychological and physical sensation outcome and ratio scores by mood**

Variable	Mood	Whole sample mean (s.d.)	Higher TAS mean (s.d.)	Lower TAS mean (s.d.)
Psychological	Baseline	151.9 (81.66)	166.6 (85.70)	132.3 (76.28)
	Sad	186.4 (93.79)	196.0 (90.11)	173.6 (102.48)
	Happy	111.3 (97.10)	100.8 (92.00)	125.3 (107.45)
Physical	Baseline	200.6 (75.50)	203.9 (71.85)	196.2 (84.34)
	Sad	204.6 (81.34)	214.5 (76.84)	191.3 (89.88)
	Happy	163.1 (79.52)	174.8 (67.82)	147.7 (94.92)
Ratio Psychological / physical	Baseline	0.78 (0.380)	0.83 (0.336)	0.73 (0.446)
	Sad	0.98 (0.448)	0.94 (0.385)	1.03 (0.540)
	Happy	0.73 (0.705)	0.54 (0.419)	0.98 (0.935)

### ***Ratio of psychological to physical sensations by mood and alexithymia group***

A ratio score of above 1 indicates greater psychological than physical sensations, whilst ratios less than 1 indicate greater physical sensations. The mean scores generally indicate greater physical than psychological sensation reporting.

A 2x2 mixed model, repeated measures ANOVA was conducted to compare ratio scores at baseline and sad mood points in relation to the TAS group. No effect of group was found ( $F(1, 19) = 0.001$ ,  $p=0.975$ ). No effect of mood was found ( $F(1,19) = 2.245$ ,  $p=0.150$ ) and the interaction was non-significant ( $F(2,19) = 0.483$ ,  $p=0.495$ ).

Given the successful change in mood manipulation items from sad mood to happy mood, a 2x2 mixed model, repeated measures ANOVA was conducted to compare ratio scores at sad and happy mood points in relation to the TAS group. No effect of group was found ( $F(1, 19) = 1.448$ ,

$p=0.244$ ). No effect of mood was found ( $F(1,19) = 3.003$ ,  $p=0.099$ ) and the interaction was non-significant ( $F(2,19) = 1.919$ ,  $p=0.182$ ).

### ***Exploring psychological and physical sensation scores for the whole sample***

No significant differences were observed in the ratio scores. It is necessary to explore this further, as there may have been no changes in ratio scores simply because psychological and physical scores were unchanged by the mood induction. To assess this, a 2x2 repeated measures ANOVA was conducted to compare mood (sad and happy, where the manipulation was successful) in relation to each sensation type (psychological and physical). This does not take alexithymia scores into account.

The main effect of mood was significant ( $F(1,23) = 14.259$ ,  $p=0.001$ , partial  $\eta^2$  0.176). There was no main effect of sensation type ( $F(1,23) = 1.490$ ,  $p=0.235$ ). The interaction however was significant at the  $p<0.05$  level ( $F(1,23) = 4.680$ ,  $p=0.041$ , partial  $\eta^2$  0.147). These effects are of medium size (Cohen, 1988). Mood induction was associated with changes in both psychological and physical sensations, both were significantly lower after the happy mood induction (mean difference for psychological 75.1, s.d. 118.42 and for physical 41.4, s.d. 52.16). There was no difference overall between scores on psychological and physical sensations. Paired t-tests, corrected for multiple comparisons (Šidák, 1967), leading to a correct critical value of  $p<0.013$ , revealed that psychological sensations changed significantly between sad and happy mood point ( $t(20)=2.906$ ,  $p=0.009$ ) as did physical sensations ( $t(20)=3.647$ ,  $p=0.002$ ). The differences between psychological and physical sensations were not significant at sad ( $t(20)=1.005$ ,  $p=0.327$ ) or happy points ( $t(20)=2.566$ ,  $p=0.018$ ). The graph suggests a trend for greater change in psychological rating than physical rating. This is illustrated in Figure 1. Participants were physically and psychologically responsive to the shift in mood from sad to happy.

In summary, the ratio scores were not significantly different in relation to mood nor alexithymia scores. However, there was a change in psychological and physical sensation reporting for the whole sample between sad and happy mood points, suggesting this manipulation did have an overall effect. Participants with MUS responded to the mood change, however did not respond to this with more physical sensations than psychological sensations.

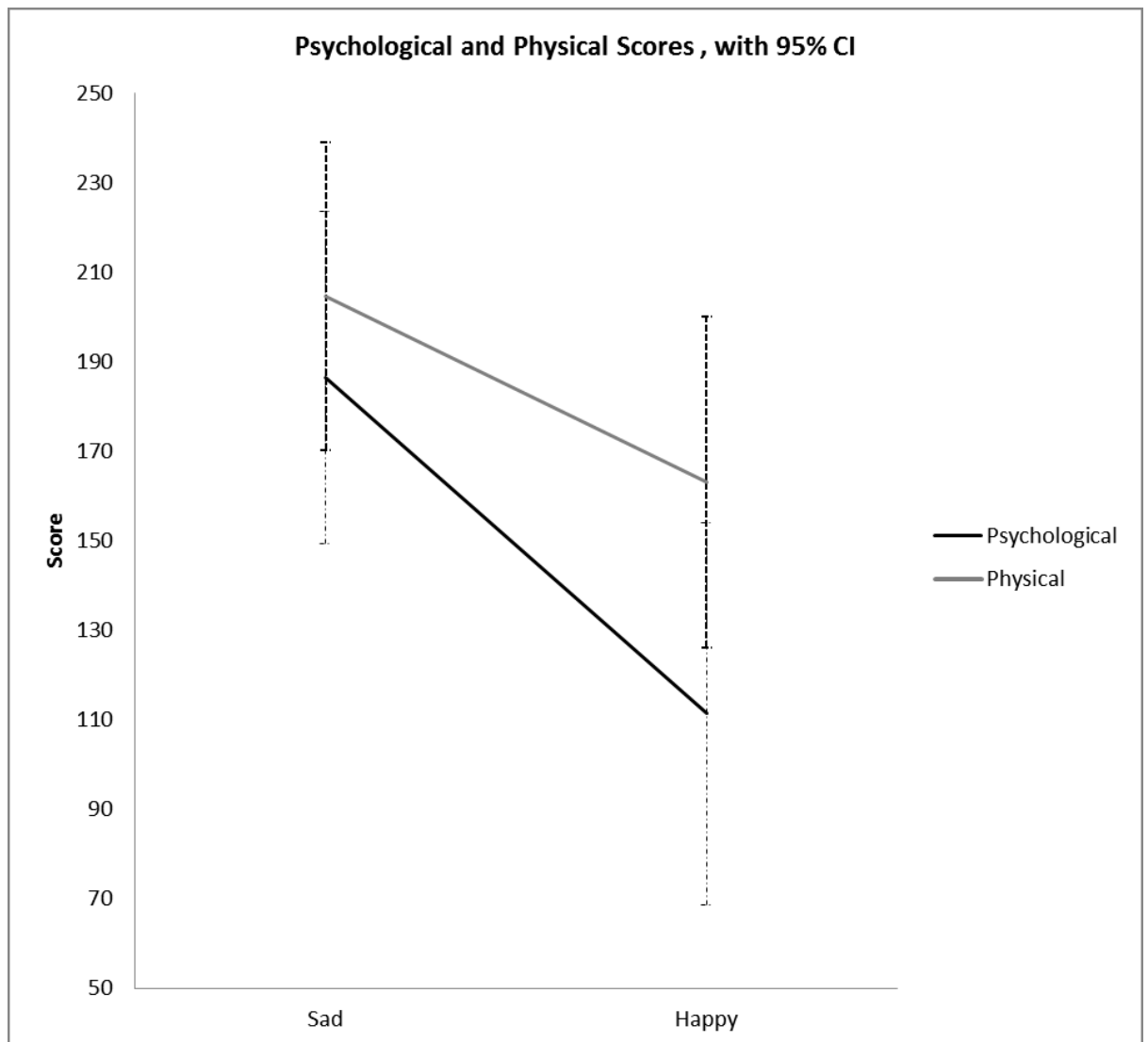


Figure 1 Graph showing psychological and physical sensation scores between sad and happy mood

### Discussion

This study examined the impact of mood change on psychological and physical sensation reporting to test the alexithymia theory of MUS. This theory firstly predicts an association between alexithymia and symptoms. Secondly, it predicts that greater change in physical than psychological sensations following mood induction (reflected in the ratio score), with a stronger difference for those higher in alexithymia than those lower in alexithymia.

Firstly, there were no significant correlations between alexithymia and experience of somatic complaint (PHQ-15 scores), depression, anxiety, health anxiety or baseline ratio of psychological

to physical sensations. In the sample of people with MUS, alexithymia does not relate to either physical or psychological symptoms. This is contrary to the alexithymia hypothesis.

Secondly, there was no significant difference in the ratio of psychological to physical sensation reporting in relation to experimentally induced changes in mood. This comparison represents a novel contribution to the research literature. There were no differences in the ratio between those with higher or lower alexithymia. The lack of difference in ratio scores was not due to psychological and physical sensation scores simply remaining static over different moods: there were significant differences in both physical and psychological sensations at sad mood compared to happy mood. The findings do not support the alexithymia hypothesis.

The alexithymia hypothesis specifies alexithymia as having a causal role in MUS. Therefore one would expect at least a moderate correlation between somatic symptoms and alexithymia scores. The results do not support this. Furthermore, levels of alexithymia were not high. In the sample of people with a MUS diagnoses ( $n=21$ ) scoring in the highest range on the PHQ-15 suggesting “severe somatisation disorder” (Kroenke et al., 2002), only two participants scored in range of “high” alexithymia, as defined by the scale authors (Taylor, Bagby, & Parker, 1997). These results differ from some previous findings that have reported higher alexithymia in people with more MUS (De Gucht & Heiser, 2003). The thesis that people with MUS are high in alexithymia is then qualified, as our (albeit small) sample consisted of people with lower scores. High alexithymia is then not necessary to diagnosis of MUS.

It was important to establish whether the mood induction was effective, as the lack of change in ratio scores could simply have been due to no impact of mood induction. The mood induction from baseline to sad mood did not appear to be effective, however comparing the sad and happy mood points did reveal change in mood. This does represent an experimentally induced change in mood, from low mood to happier mood and therefore looks at the impact of mood change rather than induction of a particularly sad low mood. As such, this also provides a test of the hypothesis as there is a significant difference in mood. Rather than creating a sad mood, it was necessary to change this to a happier mood. If the hypothesis that low mood is mistaken for the experience physical symptoms holds true, then the removal of that mood should lead to a change in physical symptoms but not change in psychological experience.

There was a significant decrease in both psychological and physical sensation reporting following reduced negative mood. The alexithymia hypothesis suggests that people with MUS are unable to detect psychological change, instead they experience these changes as physical (Taylor, 1984). Here findings show that change in mood was detected psychologically. The effect of mood change

is not different for psychological and physical sensations, as seen in the ratio scores. Reduced negative mood then was detected by our participants and the accompanying reduced physical sensations is unsurprising given the known link between mood and physical tension or pain (for example Fisher & Johnston, 1996; Tang et al., 2008). Further research with a control group could explore whether this change in physical sensations is different between those with and without MUS. This would address the issue of there being potentially a greater impact on physical sensations in people with MUS. Such an impact could be caused by either an element of alexithymia meaning some psychological experiences are mislabelled as somatic or the well documented attentional biases towards physical sensation reporting seen in people with MUS. This bias does not suggest a causal mechanism of alexithymia, rather that whilst psychological sensations are responded to, the person with MUS is also vigilant to physical changes (Barsky, 1992; Deary et al., 2007).

The characteristics of the sample show generally low levels of alexithymia in our sample. However, the participants were experiencing moderate levels of low mood and anxiety, as well as severe somatisation (Kroenke et al., 2001; Kroenke et al., 2002; Spitzer et al., 2006). AAQ scores indicated low acceptance and psychological flexibility, with the sample scores lower than a general community sample mean of 50.72 (Bond et al., 2011). Beliefs about emotion scores were higher than those reported for CFS participants (mean 35.0, s.d. 14.3) in the instrument validation study (Rimes & Chalder, 2010). This indicates highly negative beliefs about emotions. The VSHAI has no established norms however a mean score of 9.9 from a maximum of 18 indicates a degree of health anxiety, as the threshold for significant health anxiety is 8 (Salkovskis et al., 2002, Salkovskis, personal communication). The sample then had some evidence of psychopathology, low acceptance / psychological flexibility and negative beliefs about emotion which may relate their somatic symptoms and requires further research.

It must be noted that the baseline to sad mood induction did not reveal a significant change in mood manipulation check. Whilst this is a coarse measure of mood, based on only one item, the lack of effect of a well-established mood induction procedure (Clark, 1983) was unexpected. The lack of response to sad mood induction may relate to measurement error of course, or may suggest a degree of insensitivity to sad mood amongst our sample with MUS. It may be that people with MUS have an unusual relationship to mood, however there were no differences between the higher and lower alexithymia groups therefore it is unclear if alexithymia is relevant to this. Given the high level of negative beliefs about emotion, it may be that negative affect is avoided. Further research could compare response to mood induction amongst people with MUS to physically well samples with similar levels of depression and anxiety as well as healthy controls.

This study is limited by the lack of the originally planned control group. Using data from people with MUS has addressed the basic prediction of the alexithymia hypothesis, relating to the hypothesis that mood change should lead to significant changes in physical sensations over and above psychological sensations. However, inclusion of a control group would allow comparisons of the extent of these changes, as changes in physical sensations may be greater in MUS than control participants. Comparing to a control group would also have allowed investigation of whether the sad mood induction had a different effect in the MUS group. Further research with a control group (matched for similar levels of psychological symptoms as well as a healthy control), larger samples and the inclusion of more men would be recommended. The sample was smaller than originally intended, however significant changes in psychological sensations in response to mood changes provide tentative findings that are contrary to the alexithymia hypothesis. Using G\*Power (Faul et al., 2007), it was calculated that the achieved sample size ( $n=21$ ) had adequate power (above 0.8) with alpha 0.05 to detect a ANOVA effect size  $f$  of 0.3. This equates to a medium effect (medium effect defined as greater than 0.25 and less than 0.4)(Cohen, 1988). Further research could use this guidance in planning sample size calculations, powering studies to detect small effect sizes.

A further limitation is that of the inclusion only of a low mood induction and the fixed order of the manipulations. Including an anxiety induction would allow testing of the hypothesised role of anxiety in MUS. The fixed order of manipulations may have meant a carry-over effect of the sad mood on the happy mood induction that occurred for all participants. Counter-balancing of the order would improve study design, with the inclusion of a final happy mood induction at the end of the study for all participants for ethical reasons.

This study has clinical implications. High levels of alexithymia were not seen, suggesting that this is not necessarily seen in people with MUS. The formulation and treatment of MUS need not routinely focus on issues around identification of emotions or developing the use of emotion in imagination, as one may be advised to when working with a person scoring high on alexithymia (Taylor & Bagby, 2013). As there is limited evidence for alexithymia as causal in MUS, it is necessary to look elsewhere to increase our understanding. Beliefs about emotions may be relevant target for intervention, as people with MUS may have more negative beliefs, however exploring this at assessment and formulation can guide clinical intervention at an individual level. The sample did not have high alexithymia scores, however they did report high depression, anxiety and health anxiety suggesting there may be an unusual relationship with emotions or an important role for emotions in MUS, however the role of alexithymia is not upheld.

In conclusion, this experimental study found no evidence to support the causal role of alexithymia in MUS. The sample did not have high alexithymia scores, despite severe somatic symptoms.



Responses to mood change did not differ by alexithymia scores. People with MUS responded both psychologically and physically to mood change, which is contrary to the alexithymia hypothesis.

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**Executive summary of the Main Research Paper**

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There are a number of conditions with physical symptoms that do not have a known medical cause. These are sometimes referred to as “medically unexplained symptoms”, covering conditions such as chronic fatigue syndrome and fibromyalgia. As there is no known medical cause, some researchers have sought alternative explanations. These conditions cause disability, absence from paid work, use of healthcare services and cost to the economy. There is therefore an imperative to address the individual health needs and public health impact of these conditions. To do this, it is important to understand what underlies the conditions.

There is an idea that people who cannot express their emotional distress instead experience this distress as physical symptoms. This is referred to as the process of “somatisation”. Difficulties in being able to identify, describe and / or express emotions is known as “alexithymia”. It has been proposed that this difficulty in talking about psychological state causes emotions to remain unexpressed and this inexpression causes the physical symptoms of “medically unexplained symptoms”. This proposal suggests links between “medically unexplained symptoms”, alexithymia and a physical rather than psychological response to stress. Research has supported the idea that people with high alexithymia do experience greater physical arousal (greater increased heart rate and more cortisol response, a hormone activated by stress) to stress or changes in mood than people with low alexithymia. Some findings suggest that people with medically unexplained symptoms do have higher alexithymia. However, to date, no research has connected the three elements together.

This study explores the proposed links between response to changes in mood, alexithymia and “medically unexplained symptoms”. First, measures of alexithymia, depression, anxiety, health anxiety, physical symptoms, psychological flexibility and baseline psychological and physical sensations were completed by 21 participants with chronic fatigue syndrome and / or fibromyalgia. Second, the participants took part in an experimental study. They were divided into people with higher and lower alexithymia. They rated their physical and psychological sensations at baseline, following a procedure designed to induce a temporary sad mood and again following a procedure designed to induce a temporary happy mood. Mood was induced using appropriate music and instructions to bring to mind memories and images that relate to the mood. A ratio score was created by dividing psychological sensations by physical sensations. The alexithymia hypothesis would predict that people with “medically unexplained symptoms” will have a ratio that reflects more physical than psychological sensations following sad mood induction and changes in mood will be more physical than psychological. These differences should be greater in people with higher alexithymia: people higher in alexithymia response to mood change will be more physical than those lower in alexithymia.

The results showed first that there was no correlation between alexithymia, depression, anxiety, health anxiety, physical symptoms and baseline psychological and physical sensations. Second, there was no effect of the mood changes on the ratio score of psychological over physical sensations. There were no differences in this ratio between those with higher or lower alexithymia. We found that our sample of people scoring high on measures of physical symptoms, overall the levels of alexithymia were not high (as defined by the designers of the scale used). The sad mood induction did not appear to be successful, however there was a change in reported mood from sad to happy states. No changes in the ratio scores could of course be because the mood change left both psychological and physical sensations unaltered. To rule out this possibility, the psychological and physical sensation scores were assessed independently across the sad and happy mood states. Both psychological and physical sensations changed: in happy mood both were reduced.

Alexithymia levels were not associated to either physical or psychological symptoms, suggesting alexithymia is not at the root of “medically unexplained symptoms”. Changes in mood were not responded to more physically than psychologically. Contrary to the alexithymia hypothesis, people did identify changes in psychological sensation following the mood induction. High alexithymia is not necessarily seen in people with “medically unexplained symptoms”. We found no support for the alexithymia hypothesis. Our conclusions are tentative owing to a small sample size and no comparisons to how people without “medically unexplained symptoms” would respond.

The ideas from the alexithymia hypothesis remain common in practice, both general practice and across mental health teams. The lack of firm evidence for this hypothesis should be communicated to practitioners in order to guide formulation and treatment. Treatment of people with “medically unexplained symptoms” should not focus on alexithymia, not least as alexithymia does not appear necessary to have the conditions. The sample did have high scores on depression, anxiety, health anxiety, negative beliefs about emotions and low psychological flexibility. Further research could explore the role of these variables in “medically unexplained symptoms”.

**Connecting narrative**

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## **Outline**

This reflective narrative relates to the three research components (literature review, service improvement project and main research project) and the five case studies. First, general issues are considered, highlighting the rationale for choice of the studies and overall reflections. The links between the three projects are outlined, as are plans for future research. Next, elements of ethical considerations, process of research and alterations to plans, reflections and impact on practice of the literature review, service improvement project and main research project are considered in turn.

## **General observations**

The literature review focuses on the cultural applicability of the cognitive model of post-traumatic stress disorder (PTSD) and treatments, including a meta-analysis. The service improvement project concentrates on applying illness perception theory to engagement in relation to psychosis, using framework analysis of qualitative data. The main research project is an experimental study exploring alexithymia, mood change and physical and psychological sensation experience in medically unexplained symptoms (MUS). Each of these projects included research methods that were new to me. I was interested in developing my literature reviewing skills to include meta-analytic techniques. The use of framework analysis was motivated in part by a desire to gain familiarity with an analysis method for qualitative data that is strongly focused on providing insights for intervention. Finally, the main project was the first experimental piece of research I have conducted with a clinical sample. As such, I have developed skills in research analysis methods and also experimental design.

The three topics of trauma, psychosis and medically unexplained symptoms are presentations commonly seen in adult mental health practice. Through these research projects, I have gained a useful knowledge of the background literature. There is a clinical link between these topics, as the role of traumatic experience is acknowledged not only in PTSD but also in psychosis and MUS. Further, given my interest in cross-cultural practice, both the PTSD literature review and the MUS study are relevant. I was initially interested in “somatisation” and MUS having read about the different level of somatic symptom reporting co-occurring with depression cross-culturally and the concept of this perhaps reflecting a cultural-idiom of distress (Kirmayer and other’s work). At the time of writing, I am soon to commence a placement working with clients from cultures other than my own who have experienced torture. I feel the work around cultural issues will be directly useful in this placement, as will my learning from the service improvement project around engagement issues.

The research topics address different stages of a client’s trajectory and a researcher’s understanding of a topic: from understanding of the condition; to engagement and acceptability of intervention;

and then adaptations and applications of models and intervention. The main research project addresses issues around conceptualising a condition. The service improvement project explores engagement and potential acceptability of applying theory to practice. The literature review explores adaptations and applications of clinical models and interventions. I have therefore been able to reflect on different elements of both the client experience and stages of clinical research from initial theory development and conceptualisation through to intervention design and adaptation.

The case studies gave me an opportunity to consider single case design. I used multiple baselines to address considerations around stability at baseline. I applied simple pre-post designs during the course of regular clinical practice, and include measures of variables relating to potential mechanisms of change (Case study 4). The case studies also gave me the opportunity to develop formulation skills, using hypothesis testing and relating findings to the research evidence. The opportunity to consider the same case from multiple theoretical perspectives (Case study 5) was particularly useful for developing formulation skills across a range of models. These are approaches I will continue to apply as a qualified clinical psychologist. I used session by session monitoring (Case study 3), which I found helpful to guide intervention. Although this approach is unlikely to be appropriate for all cases, I hope to apply this in practice also.

I have always been committed to research, which in part what motivated me to train on the Bath course. I would ideally like to develop a career that includes a substantial research component. Given the pressures on newly qualified Clinical Psychologists to focus on supervision and client work, I imagine that initially my clinical research will focus on small scale service developments. I also would hope to use some CPD time to continue writing literature reviews, which I value as this can ensure I remain up-to-date in relation to evidence for interventions, for example. This will help me to consolidate my clinical skills also through ongoing learning.

## **Literature review**

### **Process**

The literature review focused on evidence around the applicability of the cognitive model of PTSD and the efficacy of cognitive-behavioural interventions in sub-Saharan Africa. The idea for the review was my own, based on an interest in the application of psychological theory in low resource settings and cross-culturally. My supervisor, Dr Ailsa Russell, aided me in defining what interventions were included. From this, I developed and conducted the literature searches. A previous colleague, Ms Claire Bourne from Coventry University, acted as second reviewer for decisions around including studies, data extraction and risk of bias analysis. Dr Russell and Prof Salkovskis checked the meta-analysis. Dr Russell provided detailed input to help me develop the final version of the report.

### **Outcome**

I am in the process of submitting this paper for publication. This paper relates to my personal career goal of contributing to global mental health research. Publication of this paper would add experience that may help me secure either research or practice experience in this context.

### **Personal reactions and reflections**

I felt frustrated by the lack of high standard research addressing the topic in an area of high need. Inequality is stark and non-evidenced treatments are been delivered in sub-Saharan to people in distress. The design and delivery of evidenced-based intervention is for me a foundation of clinical psychology. I realised the passion I have for this topic and feel inspired to seek ways to address this in my future career.

### **Practice impact**

Findings around cultural adaptations prompted me to reflect on the possible importance of also adapting intervention process, such as attending to how affect may be expressed and for any group work considering how stigma around mental health may prevent people from sharing their experiences. I also have gained insight into how the definition of the problem itself is in part culturally determined. At the time of writing, I am due to commence a placement with “Freedom from torture”, working with clients who are refugees or asylum seekers with PTSD. This review has highlighted to me the importance of adapting content to avoid idioms from my culture and to explore with clients metaphors from their own culture.

## **Service improvement project**

### **Ethical and other approval processes**

It was necessary to gain NHS research ethics approval to collect data from service users. Owing to problems with recruitment, I applied for a substantial amendment to add in recruiting service users from current caseloads. This was time-consuming and I have learnt the importance of covering all relevant options in the initial application. Research and Development (R&D) approval was gained through the service trust (2gether). Again, this was time-consuming and I have learned to allow more time for these processes, beyond the predicted turn-around times given.

### **Process and adaptations**

The generation of the idea was my own. Discussion with my university supervisor, Lorna Hogg, and Dr Hannah Steer (who has worked in the service and researched the impact of illness perceptions on engagement) re-scoped the work to be of appropriate size, as I had originally hoped to develop and test a short intervention. Data were collected with help from the service manager and the lead of “GRIPPERS” charity. I collected and analysed all the data, preparing the initial report. Lorna Hogg provided input to refine the final report.

### **Service user involvement**

I met with a previous service user to discuss ideas for the project and refine interview prompts. This service user, who wished to remain anonymous, gave me enormously helpful insight and helped me to consider engagement as an ongoing process, rather than something taking place at the start of intervention. The GRIPPERS charity is composed mainly of family members of service users. They were also consulted at the start of the project to seek their opinion on the work’s relevance, importance and timeliness.

### **Outcome and feedback**

The service provided positive feedback, stating that engagement is one of their key priorities and they felt acknowledgement of existing good practice and practical ideas for further development were of relevance and interest. The service was undergoing changes in its management, delivery and location. Changes in service structure and ongoing pressures around tendering, have delayed implementation of findings. Staff changes, particularly of the Clinical Psychologist, have also limited implementation.

The experience has emphasised to me the difficulties of implementing change without being part of the service or without having a person championing the change. Nevertheless, the service manager provided positive feedback, suggesting further development of intervention to train staff to use the

illness perception concepts in a semi-structured discussion with service users. It is likely that such development would require funding and / or a staff member from the service to be able to develop this as part of an existing role. We are currently exploring options to develop the work further, possibly with the involvement of another Trainee Clinical Psychologist to develop the work as their service improvement project.

### **Personal reactions and reflections**

I had originally wanted to do a larger piece of work around developing and testing an intervention. My enthusiasm for this work initially made it hard for me to see the practical challenges. I learned the importance of understanding the team context. This team was undergoing significant and difficult changes to their structure and location. In addition, psychology was not yet fully integrated, therefore psychological work was not prioritised. The team have a sizeable and challenging clinical caseload, limiting their opportunities to be involved with the project. I learnt a great deal about the importance of developing relationships with key team members to gain support and for them to be able to advocate the work. I also noticed the impact of not being physically present within the team, except for one team meeting and occasional visits for interviews. This was owing mainly to the other commitments and not being on placement with the service. I am aware that many qualified posts are split across locations and teams, and am more cognisant of the need to prioritise relationship building should I end up working in that way.

### **Practice impact**

I gained many insight from GRIPPERS, the service users and staff than I was able to include in the formal write-up. The importance of normalising experiences was very clear. I learnt about how frightened service users and family may be by their experiences. I recognise that empathising and normalising are vital stages of early engagement. I was able to put this learning into practice with a client in my clinical health placement who was hearing voices following a trauma relating to their physical health. The client was unable to understand the “identity” of this experience and had struggled to engage with services in the past. Emphasising that this experience is of course frightening however offering a frame to understand this within helped me to engage with the client.

Listening to GRIPPERS and service user stories helped me to remember the human distress caused by both experiences of psychosis and experiences of hospitalisation. Hearing about the reality of these experiences reinforced to me the importance of keeping service user experience in mind, whilst also seeking to provide interventions based in evidence.

## **Main research project**

### **Ethical and other approval processes**

I gained NHS research ethics approval. It was important to include within the information sheets some details of the mood induction procedure, however the purpose of the study was not fully described. I used guidelines from the ethics system (IRAS) to ensure that I explained to participants that they would not receive a full briefing, however would be fully debriefed. It was also necessary to allow participants 24 hours from receiving the information sheet to providing consent. Ethical approval was gained in a timely fashion. Gaining R&D approval was time-consuming, partly because approvals were sought during summer months, leading to substantial delay owing to R&D staff and committee availability. I gained R&D approval from North Bristol NHS Trust, Royal National Hospital for Rheumatic Diseases NHS Trust, Avon and Wiltshire Partnership Trust and 2gether Trust. I have learned to allow more time for these processes.

### **Process and adaptations**

The idea was developed with input from my university supervisor Prof Paul Salkovskis. The detailed protocol also had input from my field supervisor Dr Jeremy Gauntlett-Gilbert. Staff at the Royal National Hospital for Rheumatic Diseases in Bath and at the CFS/ME clinic at Frenchay Hospital were instrumental in helping me to recruit patients with fibromyalgia. Dr Jonathan Freeman was able to give me access to IAPT groups of relevance, including mood and fibromyalgia groups. Through Dr Freeman and his staff, I was able to seek to recruit participants with low mood, anxiety or fibromyalgia. I collected and analysed all the data. I discussed plans for analysis with my supervisors. I wrote an initial draft of the report and my supervisors provided input to help me develop the final version.

As outlined in the report, there were substantial difficulties with recruitment for the control group. Local IAPT services in Bristol and Bath were undergoing changes in commissioning and restructuring at the time of recruitment. As such, they were unable to assist in the project. The practical difficulties of travelling to Swindon and Gloucester to recruit limited the number of groups I was able to attend to advertise the project in the time available to me. Despite this, I attended eleven groups, reaching around 90 potential participants face-to-face. I also placed advertisements for the research in venues across Bristol and Weston-Super-Mare where the local IAPT groups meet. I also placed adverts across local GP surgeries, pharmacies and with the university's student counselling service. I contacted local mental health support groups and charities, however this did not prove fruitful. For the MUS group, I was able to gain participants through the NHS services and contacted local CFS and fibromyalgia charities and support groups.

As it was necessary to allow participants 24 hours from receiving the information to agreeing to take part, many people who expressed initial interest at the group meetings were then unavailable or had lost interest by the time of contacting them to gain consent. Several people described not wishing to participate owing to concerns about the mood induction procedure. I was approaching people who were all towards the end of their mood management intervention and several described the skills they had learnt as feeling new and fragile, therefore not wishing to do anything at this stage that they felt may cause them upset. The wording in the information sheet was written so as to reflect the potential risks, as is necessary to gain ethical approval. This may have communicated an inflated sense of risk to potential participants who were particularly concerned about their mood. Additionally, the practical issues of needing to meet face-to-face with participants to collect data lead to several people withdrawing interest. In future, I will explore ways to include online data collection opportunities, considering the potential impact this may have on data quality.

The difficulties in recruitment lead to changes in the research design. We were able to test elements of the original research hypotheses, however without a control group. Disappointingly, this limited findings.

There are two issues relating to limitations of this project for reflection. First, in design, we chose a low mood induction task rather than a stress / anxiety induction task that might more obviously relate to the stress-alexithymia hypothesis. This was really for two reasons – advise that the low mood induction would also induce stress and the opportunity to be the first study to assess whether low mood is related, through alexithymia, to the reporting of symptoms. It would have been ideal to have both, together with the happy mood induction and to have presented these in a counterbalanced order to all participants. The second limitation relates to issues during recruitment. In order to comply with ethical procedures, it was necessary to name that the study related to mood on the posters and provide details in the participant information. It is entirely possible therefore that those with high alexithymia self-selected themselves out of the study as it is possible that a poster advertising a mood study to people who have difficulties identifying their feelings would not be appealing to them. I have learnt from this that further consideration should be given to the advertising materials. I lost several potential participants having given them the participant information sheet, with several people reporting they were not interested as it sounded too upsetting. This is of course entirely appropriate however highlights the practical challenges around doing mood research with people who may have difficulties identifying their moods or perhaps a fear of feeling too sad after the mood induction.

## **Outcome**

The findings of the project are limited by the practical difficulties in recruitment. Nevertheless, I plan to submit a brief report for potential publication.

## **Personal reactions and reflections**

The key lesson for me was around the importance of engaging services in supporting research. I will plan this into future research projects at design stage.

I was curious to explore the alexithymia hypothesis. I met clinicians with strong views around this hypothesis and found it important to remain openly curious. During applications for R&D approvals, I met clinicians who were acting as gatekeepers. The process of demonstrating good research knowledge, sound ethical principles and making clear the minimal impact of the research on service staff was something I had to practice. I feel this helped me to develop transferable professional skills regarding presenting ideas and making a case for change.

## **Practice impact**

Debriefing participants required me to sensitively present ideas around the role of alexithymia in MUS. For some participants, these ideas were experienced as difficult to hear and contrary to their own beliefs and I was able to briefly explore their own conceptualisations. This experience was similar to suggesting formulations which clients may find difficult to hear and working collaboratively with clients to explore reasons for this difficulty and / or alternative conceptualisations. Simply repeating this process has developed my confidence and I feel more able to openly explore and develop shared formulations with clients in clinical practice.

In summary, the research I have engaged in has broadened my experience of design and methods for clinically relevant research. I have developed as a clinical psychologist in training as these experiences have shown me the importance of the scientist practitioner model. I have a greater understanding of the complex nature of clinical research settings, with the dependence on clear ethical practices and collaborative working relationships. This is of course rarely represented in the concise and precise research papers which inform my clinical practice and knowledge of theory. My interest in clinically relevant research and practice in non-Western settings has developed further, and I anticipate significantly greater challenges in attempting this work than within the structures of the NHS. My commitment to evidence-based practice and research as part of the Clinical Psychologist's role however continues to motivate me to develop such practice and research cross-culturally.



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## Appendix 1: Data Extraction Tools for Systematic Review

Data Extraction Tool used for all parts of review:

Record no		1 <sup>st</sup> Author	
Title			
Model?	Intervention?	CBT?	
Nation			
Sample			
Study type & design			
Model finding (include which part of model and describe findings in full)			
Intervention description			
Comparison description			
Sample sizes			
Diagnosis			
Therapist details (qualifications, training?)			
Cultural adaptations? (describe)			
Outcome measure (name, validated, translated?)			
CBT components?			
Follow-up data provided? (timescale)			
Other comments			

Study	Intervention described by authors as	Comparison intervention / wait list	Outcome Measure	Post-intervention time given?	TREATMENT Mean	SD	N	CONTROL Mean	SD	N	Follow-up time given?	TREATMENT Mean	SD	N	CONTROL Mean	SD	N
<b>EXAMPLE</b> 1430 O'Callaghan	15-session, manualized, culturally modified, trauma-focused cognitive behavioral therapy intervention. The manual was based on "A Web-based learning course for Trauma-Focused Cognitive Behavioral Therapy" Included - introduction (ground rules, psycho education on rape and trauma, and a safe place); stress management (controlled breathing, progressive muscle relaxation, and thought stopping); feelings (affect expression and modulation); cognitive coping (the cognitive triangle, the relationship between thoughts, feelings, and behavior; trauma narratives; and identifying and changing in accurate or unhelpful cognitions. Delivered in a group and three individual sessions.	WLC	UCLA PTSD Reaction Index (Revised);	post intervention = 7 weeks	UCLA-PTSD RI = 18.38	10.53	24	42.93	13.67	28	3-month follow-up	15.08	8.79	24			

Tool used to extract data for meta-analysis, with completed example

Risk of Bias Tool (Taken from Higgins et al., 2011).

**Study**

	<b>Judgement</b>	<b>Support</b>
Random sequence generation		
Allocation concealment		
Blinding of participants and personnel		
Blinding of outcome assessment		
Incomplete outcome data		
Selective reporting		
Other bias		

## Appendix 2: Service Improvement Project – Example tabulated results reflecting the framework analysis in more detail

Typically in framework analysis, each participant's data is analysed in relation to the framework (Ritchie & Spencer, 1994). Here, owing to the complexity of the framework, participant data is integrated into the overall framework that covers the code and instances this is referred to as a facilitator or barrier. Brief examples of the types of data relevant to each code are presented in Table A1.

**Table A1 Selected data to illustrate how each code discussed**

Level	Code	Facilitator to engagement	Barrier to engagement
Social	Stigma	-	<p>A <u>stigmatising</u> venue can be a problem. (Staff).</p> <p>Hard to come to terms with the <u>stigma</u> of it (Carers).</p> <p>The <u>stigma</u> of mental health is still very strongly there and it's not going anywhere soon but it meant (Service user).</p>
Service	Hospitalisation	-	<p>Perceptions - so you're here to <u>put them in hospital</u> which is a very strong feeling particularly for people who have had some contact with mental health (Staff).</p> <p>Suddenly you're in hospital and you're surrounded by other unwell people of all age groups, screaming and shouting, very distressed and <u>it's just an awful experience</u>. (Staff).</p> <p>About the fear of <u>going to hospital</u>, maybe about telling people that going to hospital is not an inevitable, it's not inevitable that you'll go to hospital. (Service user).</p>
Service	Resources	-	<p>I think the <u>environment</u>...our <u>buildings</u> are not really up to scratch, they are not great places to bring people in to, or it might be if they are at home, I think that can be difficult (Staff)</p> <p>Money for petty cash for transport (Staff)</p> <p>Faceless person above [the</p>

Level	Code	Facilitator to engagement	Barrier to engagement
			ground staff] <u>controlling the money</u> , making changes in the system, and health policy changes, so the service gets diluted across the are (Carers).
Service	Staff management	<p><u>Multidisciplinary team</u> is crucial for OT, physio, psychology, doctors and nurses. (Staff).</p> <p>Service users can be a bit chaotic so we need regular contact, <u>flexibility and a lower caseload to accommodate</u>, especially with the travelling. (Staff).</p> <p>[Talking about an old <u>training</u> course in engagement ] It was useful to learn about and think about validation of emotions, things like that (Staff).</p>	<p>There is a <u>huge pressure on us to complete assessments</u>, measures ... I wouldn't necessarily do those to begin with because I want to create a rapport (Staff).</p> <p>We don't do any <u>specific training</u> on engagement, you either just pick it up or you do it already. (Staff).</p> <p>It's very difficult with a <u>high case load</u> to maintain your standards of care (Staff).</p> <p><u>People change in the staff team</u> (Service user).</p>
Service	Other management	<p><u>Less red tape really</u> ... we've got an open referrals system so they can phone us up. (Staff).</p> <p><u>Rio</u> can help with engagement ... it certainly <u>allows us to share the information more quickly</u>, certainly around the team (Staff).</p>	<p>Still happens, is that people go in to initial assessments or <u>continuing on without looking at the information</u> that they have got to hand and I think it really, I understand it, would that, people are like I've given you all this information and now you are asking it all again. (Staff).</p> <p>When <u>decisions</u> about treatment are <u>not shared</u>, sometimes it's just not clear, it's all down to the person [staff member] (Carers).</p> <p>As a parent you are <u>morally responsible but not privy to the information</u> (Carers).</p>
Staff	Characteristics	<p>A shift from would you like to we are going to, you need a <u>bit of charisma</u>, a bit of get up and go to get them engaged (Carers)</p> <p>The staff, they are <u>great people, with great people skills</u>. They spoke to you like a human being. They still treated you as a person and tell you when you are being all weird! (Service user ).</p> <p>So <u>friendly, so helpful</u>, so I didn't</p>	-

Level	Code	Facilitator to engagement	Barrier to engagement
		think anything like about not wanting to get, to use, to engage I guess (Service user).	
Staff	Arrangements	<p>For the majority of people it's <u>regular contact and prompting</u>...maybe <u>a text message to prompt</u> on the day, something that jogs their memory. (Staff).</p> <p>Set up the initial assessment at a <u>time and venue that suits them</u> (Staff).</p> <p><u>Routine and stability</u> is what is needed, with consistency (Carers).</p> <p>It was a while before they like did anything, they were just coming to visit, that <u>unstructured approach helped</u> and the company, it made it less scary, to have someone with you right from the start (Service user).</p>	-
Staff	Flexibility	<p>Having that <u>flexibility</u> I think and you know if someone <u>misses six appointments</u> we kind of kind take of more assertive approach to follow-up. (Staff).</p> <p><u>Flexible timings</u> because young clients may be in school (W).</p> <p><u>Flexibility</u> from the staff is important, <u>an option to go out</u> and have normal, normality is needed, a normal relationship with staff, do normal things (Carers). [“<b>Normalising</b>” also].</p> <p><u>Flexibility of how meet up</u> (Service user). [“<b>Arrangements</b>” also].</p>	Barriers would be about being <u>inflexible with regards appointments</u> , having to attend a certain place that might be a distance (Staff)
Staff	Relationship	<p>Sometimes things about <u>gender</u>, the gender of the assessor, might not be <u>culturally appropriate</u>. (Staff). [Service user made similar comment].</p> <p>Seeing the same person, <u>building that relationship</u> and knowing that was going to happen (Service user).</p> <p>They always make you feel as if you mean something, <u>someone to</u></p>	<p>Asking streams of questions without clarifying <u>how they feel</u> about that, we always say to people you know if you want a break, tell us...It's where people just ask question after question and there is no <u>sense of how that is for that person</u> and just saying well I can see that this is really difficult for you (Staff).</p> <p>There's a lot of questions you</p>

Level	Code	Facilitator to engagement	Barrier to engagement
		<p><u>go to who you trust</u> (Carers).</p> <p>The first session is very much about making the <u>person feel comfortable</u> so it's about <u>using the language</u> that they feel comfortable and that, so a degree of informality and so explaining what we are there to do but judging it very much on the individual (Staff). [<b>"Person centred"</b> also].</p> <p>Lots of work to build <u>rapport</u> ...the rapport helps us stay in touch (Staff).</p> <p>It's their approach, they are like <u>trying to understand you</u> and friendly and you get the impression that they know, know where you are coming from (Service user).</p> <p>That <u>first approach</u> was vital, that first person. Their approach, <u>friendly</u> and made for you, really helped me to recover. So I engaged. (Service user). [<b>"Person centred"</b> also].</p>	<p>know they meet with us and there might be risks and we have to involve crisis and treatment teams <u>so that's more questions</u> (Staff).</p>
Staff	Showing usefulness	<p>It's about them talking to us about what sorts of things we might <u>be able to do to help</u>. (Staff).</p> <p>Practical work is particularly key if they are really angry...you walk through the door and go well <u>what can I do for you today</u> and it's like well I need somewhere to stay tonight so it's sorting that out (Staff).</p> <p>GRIP make sure the <u>practicalities</u> get dealt with (Carers).</p> <p>The staff were <u>fighting along with me</u>, in my corner to help with [some family issues]. ..<u>seeing that they can help you</u> with the things that matter in life, like my family, that helped me engage (Service user).</p>	-
Staff	Person centred	<p>The key for engagement, well, it should be about <u>what's important to the service user</u>. (Staff).</p>	<p>Not taking <u>wishes into account</u> (Service user).</p>



Level	Code	Facilitator to engagement	Barrier to engagement
		<p><u>Doing what they like</u>, going to the cinema, helping then access food, benefits and accommodation, because that stuff is stressful and baffling, so it's practical, hands on engagement right from the assessment stage. (Staff).</p> <p><b>["Normalising", "Showing usefulness" and "Practical" also].</b></p> <p>You don't have to tell me anything, acknowledge that you don't know me but that you do have my <u>best interests at heart</u> (Service user).</p>	
Family	Family	<p>It peripherally helps <u>support parents</u> so that they know about psychosis and they can offer than support the other 23 hours of the day when we are not there. (Staff).</p> <p>When we are talking about the literature...well it's the <u>carers</u> really and that's a tricky one about engagement because sometimes they don't want too much involvement...but if <u>we give them some information</u> then they are really grateful because it really brings the stress down so it's kind of looking at the broader picture I guess of things in the household really. (Staff).</p> <p>Making sure the <u>carers are getting support</u> and making sure they are getting the opportunities to have breaks and stuff (Staff).</p> <p><u>Use the family</u>, they have the most knowledge about the person who is unwell (Carers).</p> <p><u>Mum helped</u>, she has [health condition] and put off getting help and so she really pushed me to get help. You know, that general Mum intervention, it's the best, putting her foot down (Service user).</p>	-
Individual	Lifestyle	The <u>client's own background</u> – I was brought up to engage and respect authority. (Service user).	I think the difficulties come with <u>drugs and alcohol</u> , that that makes life more chaotic and

Level	Code	Facilitator to engagement	Barrier to engagement
			<p>difficult to get hold of (Staff).</p> <p><u>Substance use</u>, there was lots of it and it gets in the way (Carers).</p>
Individual	Worries	So taking individual beliefs into account, like <u>suspiciousness</u> etc and thinking about the anxiety levels when setting things up (Service user).	<p>I've known patients who really enjoy activities and social interaction but <u>sometimes anxiety will get in the way</u>, they perhaps might start to convince themselves that they shouldn't go to the group because of some random reason, something more important. (Staff).</p> <p>I wasn't <u>listening, trusting or believing anyone</u> and in that tricky position and my thoughts were messing me around shall I say, I wasn't having a grip of reality and I thought people could hear my thoughts and wondered, <u>worried</u> why they really wanted to know from me (Service user).</p>
Individual	Reject illness	-	<p>For some people it's avoid sort of thinking, <u>it's not happening to me</u> I don't need to do this or it's more negative, they might feel that they don't deserve that they've got negative thoughts perhaps and those thoughts mean they shouldn't go and have fun and do something positive. (Staff).</p> <p>We never knew he was ill, he was very private, <u>hide everything</u> and he got back to work after recovery... <u>he did not want to admit he was unwell...</u> he kept active and could mask it, with the GP, so he didn't get into the special services (Carers).</p> <p><u>I didn't believe I was ill</u>. My own beliefs got in the way (Service user).</p>
Perception	Identity	It's about education you know about mental health and mental illness so that they <u>can understand what's happening</u> to them really, you know they haven't got much	<u>How they present psychosis</u> to a young person. It's absolutely petrifying that this diagnosis sticks with them and everyone thinks oh well you're mad and

Level	Code	Facilitator to engagement	Barrier to engagement
		<p>insight (Staff).</p> <p>Quite often we'll give an information leaflet about things...I would do that about 60-70% of the time [credit-card sized information sheet]...a bit of <u>information about kind of what psychosis is</u> and what's the about. (Staff).</p> <p>I knew I had to speak with someone and they answered my questions. <u>To help me understand what was happening</u>, and how can you help me, managing those expectations (Service user).</p> <p>If they had given me at the <u>time a definition of psychosis and list of things people may do and how I fitted</u> so I can see that it fitted me, that would have really helped at the start (Service user).</p>	<p>you're going to go around killing people and so the shame that comes with that might stop them. (Staff).</p> <p>I spent all my time alone. I was very ill but <u>I didn't realise it</u>, my family called help, not me – I didn't realise (Service user).</p>
Perception	Cause	<p>People often want to know <u>why, why me</u>, why have I got this...there are a number of theories you could talk about...but er, it's about sometimes, so maybe it's about finding a neater way to do that and perhaps <u>finding a way to talk about the causality</u>...and focusing on the bits we can do something about, like we can't do anything about the genetic factors. (Staff, only comment in this category)). [<b>"Personal control"</b> and <b>"Treatment control"</b> also].</p>	<p>I did it, I spoke to them but in my eyes it wasn't a mental health team who could help, at the <u>time I thought it was a spiritual thing</u> (Service user, only person to comment in this category).</p>
Perception	Consequences	<p>I think one of the big thing is about <u>maintaining hope, that optimism</u>...If someone gets that you know <u>light at the end of the tunnel</u>, that helps. (Staff).</p> <p><u>Help them to understand they are not necessarily such big problems.</u> (Staff)</p> <p>They engage with it all when messages about the <u>risks</u> are clear (Carers).</p> <p>If the <u>consequences of it all feel too high, then everything is just too</u></p>	<p><u>I didn't think about the consequences</u> of it, because I didn't think I was ill. It only hit me, I started to think maybe I might be wrong when I saw what was happening to [family]. (Service user, only comment in this category).</p>

Level	Code	Facilitator to engagement	Barrier to engagement
		<p><u>risky</u> so if they feel lower it's easier to engage (Service user).</p> <p>I'm not sure about what about me helped, I had that initial bit where I knew it was going to be hard, <u>but it would be ok</u> (Service user).</p>	
Perception	Timeline	-	Talking about it, how it was, I just <u>thought it would be like that forever</u> but they said it would get better (Service user, only comment of this type).
Perception	Personal control	<p>Engagement is vital really...<u>giving people some control themselves</u> (Staff).</p> <p>We have the "<u>getting back on your feet</u>" information which is something that a couple of the team, psychologists, put together and that is really useful. (Staff).</p> <p>The kit, for self-soothing, that was really great, making that up for example in case you have to go in [to hospital], bits of emergency meds, like first aid, <u>meant I had a plan</u> (Service user).</p> <p>Simple ideas about <u>telling me what helps</u>, simple positive focus and not some great long speech about warning signs too early (Service user)</p> <p>Tell people straight, <u>you have the control to take these decisions</u> (Service user)</p> <p>Talked about <u>what we could do</u> to help, that it wouldn't always be like this, so dark. (Service user).</p>	It will be about whether <u>they want to be proactive</u> and what it'll be about, some people prefer just to be given medication...some people aren't prepare to do it all you know. (Staff).
Perception	Treatment control	<p>Being clear about <u>what that service is</u> and what it can do for them, we need to be clear about the role and remit of services to referrers. (Staff).</p> <p>EI can be really <u>successful treatment</u> in home environment and that can happen. That message might help, that working with the services works (Service user).</p>	-

Level	Code	Facilitator to engagement	Barrier to engagement
		They are persuaded to take medication by the <u>positive that they can leave hospital and have that supervision</u> , but it gives a sense of control to the patient, to go home and discuss the treatment all together, to feel part of the treatment and that he can influence his own care (Carers).	
Perception	Treatment concerns	Their <u>expectations and knowledge of service</u> can make a difference – do they know anyone who has been through the service, what’s their family view, family culture, how do that, that whole issue around illness, what’s that like. (Staff, only comment in this category).	<p><u>Medication</u> can be a big issue, I mean it’s a whole new area but if people feel they are not being listened to, if medication <u>regimes are not being properly explained, side effects that are being overlooked</u> (Staff).</p> <p>When they make changes, like to give them <u>cheaper medication</u>, it changes the colour of the packet, so it looks like something else and he thought it had different effects (Carers).</p>
Perception	Treatment necessity	<p>It’s about kind of trying to say to them, this is valuable <u>we are trying to do something valuable</u>. (Staff)</p> <p>They need to feel <u>positive towards the treatment</u> (Carers).</p> <p>I think it you know in the back of your mind that it’s going to help them, you just do, you just engage. Thought it was going to be hard, but <u>knowing it would help</u> helped me get through it all (Service user).</p>	The medication, it can have dreadful side effects and it’s distressing when they force medication...he did not believe the tablets helped... <u>need to have some faith in the treatment</u> , the side effects just mean they disengage (Carers, only comment in this category).
Practice	Groups	<p><u>Small groups</u>, building friendship seem to be more useful, routine and such like...that <u>support from peers</u> is quite powerful. (Staff).</p> <p>Perhaps giving some <u>examples of people who are living with the diagnosis and are successful</u> and or even examples, obviously anonymous, of people from our own practice so saying I’m come across a number of people who have gone on to finish their degree or that kind of message. (Staff). [“<b>Normalising</b>” also]</p>	<u>[Peers] are quite a big influence</u> on other patients or often they’ll meet in hospital ...that can you know give them a positive or negative picture of us. (Staff, only comment in this category).

Level	Code	Facilitator to engagement	Barrier to engagement
		<p>Meeting other <u>people with similar experiences</u>, they would understand it, it was ok to talk about stuff around people who are talking too (Service user).</p> <p><u>Having another person who'd been ill</u> and hear about that was useful (Service user).</p>	
Practice	Motivation	<p>Things like <u>motivational interviewing</u>, trying to find out what their hot spot is, you know what is it about the person that will make them decide to make a change, you know is it their health that they are worried about. (Staff).</p> <p>To me it's thinking about what the <u>hook</u> is very early on (Staff).</p> <p>Engage with <u>what makes the person tick</u>, get to know them, pick up on their interests and use those, like physical activity or occupational things (Carers).</p>	-
Practice	Activity	<p><u>Activities</u> that are service user led, what they need at that time, making that available to them, it might be something then they move on to something more structured (Staff).</p> <p>Keeping them <u>involved in doing something</u>, something they like, it helps, but if they are inactive, the symptoms get worse and they drop out (Carers).</p> <p>We would go and <u>walk into town</u> and have a coffee, it built my <u>confidence</u> (Service user).</p> <p>To engage people, go to them, <u>do something active</u>, find things that are relevant and give them their own voice (Service user)</p>	<p>Ideas about <u>what the activity is</u> you know ...people who have similar sorts of worries and issues in terms of what they do and just try to help them understand that. (Staff). [“<b>Normalising</b>” also]</p>
Practice	Tailored	<p>The approach being very much, being very aware of <u>how they are feeling and the position that they are in</u> (Staff).</p> <p>Psycho-education is <u>tailored</u>, to be less scary (Staff).</p>	-

Level	Code	Facilitator to engagement	Barrier to engagement
		<p>Treat people <u>as individuals</u> with intelligence, as a personality not a case (Carers).</p> <p><u>Tailoring</u> the question (Service user).</p> <p>They don't have like one specific one of dealing with the patient or client, they design their approach sort of like with each individual <u>with each individuals needs at heart</u> (Service user). [<b>"Person centred"</b> also].</p>	
Practice	Normalising	<p>It's about one to one, taking people out, being informal, have a coffee, maybe things like some graded exposure to catch the bus...it's important to normalise. (Staff) [<b>"Arrangements"</b> also].</p> <p>Being a bit more informal, trying to <u>normalise</u> things as best as you can, for that person and the family because it's a terrifying experience. (Staff).</p> <p>Taking an interest in people lives and not just their illness, the illness is the only thing you <u>can talk about, normal everyday life</u> get lots, it's nice to show a bit about yourself, so you're not just 100% illness, and <u>talk about normal real life stuff</u> (Service user). [<b>"Person centred"</b> also].</p>	-
Practice	Practical	<p><u>Giving someone a lift</u>, when you're driving there is much less eye contact and that seems to be really helpful, in terms of engagement. (Staff). [<b>"Relationship"</b> also].</p> <p>It's like <u>Maslow's hierarchy</u>, like where I live and I have no money, so we try to work on that first...like about safety and things ...making someone <u>feel more secure</u> is going to have a <u>big impact on their ability to engage</u> with us really. (Staff).</p>	-
Practice	Formats	You need to <u>avoid jargon</u> and reframe in their language.(Staff).	It varies with the <u>written information</u> , some people are very clear that they don't want

Level	Code	Facilitator to engagement	Barrier to engagement
		<p>A <u>standardised fact sheet</u> would be good, basic and easy to read information and about team and what we can do, it acknowledged the importance and seriousness of it all. (Staff).</p> <p>A <u>structured workbook</u> thing for use with early warning signs, we may use something like that. (Staff).</p> <p>Have a <u>summary of the questions in your head and go through it</u>, can help you [staff] to understand what's going on with this all, not showing loads of questions to everyone, not necessarily doing it as a pen and paper exercise, could, or do the discussion in a way that works for the person, like go for a walk and cover the same information (Service user).</p> <p>Some examples, from people who did well, so you can use that similar to like a <u>role model</u> (Service user)</p> <p><u>Information is key</u>, not necessarily a one way street. <u>Could be books, websites, pictures, a person</u>, in whatever format needed or they'd prefer, to understand what you are going through and to let them know (Service user).</p> <p>I was going through great distress and if <u>I'd heard others, stories of people being unwell, written down or videos or meet them or whatever</u>, that would have helped me understand what I was going through or talking to a fellow service user to help another person help understand as there will be some similarities (Service user).</p> <p><u>A mentor, of similar age who is enthused</u>, that can really help (Carers). [<b>"Groups"</b> also].</p>	<p>to read much...others even if they are saying that they don't want paper from us you can be trying to direct them to websites and things, and using things like texts and emails. (Staff).</p> <p><u>I hate questionnaires!</u> (Service user).</p>

Ritchie, J., & Spencer, L. (1994). Qualitative data analysis for applied policy research. In A. Bryman & R. G. Burgess (Eds.), *Analysing Qualitative Data* (pp. 173–194).



### **Appendix 3: Measures used in Main Research Project**

The copyrighted and paid-for Toronto Alexithymia Scale is not included here, owing to copyright law. This was the first measure completed by participants. Measures were presented on A4 paper, therefore appeared larger than shown here.

Thank you for agreeing to take part. You will be asked to complete some questionnaires. You will then take part in two tasks. After each task, you will be asked to answer some more questions. Remember: You are free to withdraw from the study at anytime. Please just let the researcher know. Please read the instructions and answer the following questions.

**A) Please put a cross on the line shown below to indicate how you feel right now.**

You are being asked to rate how much you currently feel. The line is numbered and you can place a cross anywhere on the line, between numbers if you want. A mark at the extreme left end would indicate you are not feeling the sensation / emotion at all. A mark at the extreme right end would indicate that you are feeling it extremely. A mark near the centre would indicate that you feel it moderately. Please ask the researcher if this is not clear.

Not at all anxious	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely anxious
Not at all depressed	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely depressed
Not at all physically uncomfortable	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely physically uncomfortable
Not at all in pain	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely in pain
Not at all sad	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely sad
No headache at all	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely strong headache
Not at all stressed	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely stressed
No negative thoughts at all	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely strong negative thoughts
Not all fatigued	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely fatigued
Not all worried	<div style="display: flex; align-items: center;"> <div style="flex: 1; position: relative;"> <div style="position: absolute; top: -10px; left: 0; right: 0;">0 10 20 30 40 50 60 70 80 90 100</div> <div style="border-bottom: 1px solid black; height: 10px; width: 100%;"></div> </div> </div>	Extremely worried

For researcher's use only: ID: Date:

B) Fill in the boxes to mark your answers. Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all 0	Several days 1	More than half the days 2	Nearly every day 3
H1. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H2. Feeling down, depressed or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H3. Trouble falling / staying asleep, sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H4. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H5. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H7. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H9. Thoughts that you would be better off dead or of hurting yourself in some way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you have been bothered by any of the 9 problems listed above, please answer the following:

How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult ☐

C) Over the last two weeks, how often have you been bothered by the following problems?

	Not at all 0	Several days 1	Over half the days 2	Nearly every day 3
G1. Feeling nervous, anxious or on edge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G2. Not being able to stop or control worrying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G3. Worrying too much about different things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G4. Trouble relaxing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G5. Being so restless that it's hard to sit still	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G6. Becoming easily annoyed or irritable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G7. Feeling afraid as if something awful might happen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you checked off any problems how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult ☐

For researcher's use only: ID:	Date:
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D) Using the scale provided, please indicate how much you have been bothered by any of the following problems.

Circle 0 if you have not been bothered at all

Circle 1 if you have been bothered a little

Circle 2 if you have been bothered a lot

		Not bothered at all	Bothered a little	Bothered a lot
S1.	Stomach pain	0	1	2
S2.	Back pain	0	1	2
S3.	Pain in your arms or legs or other joints	0	1	2
S4.	Menstrual cramps or other problems with your periods (women only)	0	1	2
S5.	Headaches	0	1	2
S6.	Chest Pain	0	1	2
S7.	Dizziness	0	1	2
S8.	Fainting spells	0	1	2
S9.	Feeling your heart pound or race	0	1	2
S10.	Shortness of breath	0	1	2
S11.	Pain or problems during sexual intercourse	0	1	2
S12.	Constipation, loose bowels, or diarrhoea	0	1	2
S13.	Nausea, gas, or indigestion	0	1	2
S14.	Feeling tired, or having low energy	0	1	2
S15.	Trouble sleeping	0	1	2

E) Below you will find a list of statements. Please rate how true each statement is for you by circling a number next to it. Use the scale below to make your choice.

1 never true	2 very seldom true	3 seldom true	4 sometimes true	5 frequently true	6 almost always true	7 always true
--------------------	--------------------------	---------------------	------------------------	-------------------------	----------------------------	---------------------

1. My painful experiences and memories make it difficult for me to live a life that I would value.	1	2	3	4	5	6	7
2. I'm afraid of my feelings.	1	2	3	4	5	6	7
3. I worry about not being able to control my worries and feelings.	1	2	3	4	5	6	7
4. My painful memories prevent me from having a fulfilling life.	1	2	3	4	5	6	7
5. Emotions cause problems in my life.	1	2	3	4	5	6	7
6. It seems like most people are handling their lives better than I am.	1	2	3	4	5	6	7
7. Worries get in the way of my success.	1	2	3	4	5	6	7

For researcher's use only: ID:

Date:

F) Please tick the column that best describes how you think. Please note that because people are different, there are no right or wrong answers to these statements. To decide whether a given answer is typical of your way of looking at things, simply keep in mind how you think most of the time.

	Totally agree	Agree very much	Agree slightly	Neutral	Disagree slightly	Disagree very much	Totally disagree
0551 It is a sign of weakness if I have miserable thoughts.							
0552 If I have difficulties I should not admit them to others.							
0553 If I lose control of my emotions in front of others, they will think less of me.							
0554 I should be able to control my emotions.							
0555 If I am having difficulties it is important to put on a brave face.							
0556 If I show signs of weakness then others will reject me.							
0557 I should not let myself give in to negative feelings.							
0558 I should be able to cope with difficulties on my own without turning to others for support.							
0559 To be acceptable to others, I must keep any difficulties or negative feelings to myself.							
0560 It is stupid to have miserable thoughts.							
0561 It would be a sign of weakness to show my emotions in public.							
0562 Others expect me to always be in control of my emotions.							

For researcher's use only: ID:

G) Each question in this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings over the past six months.

Identify the statement by ringing the letter next to it, i.e. if you think that statement (a) is correct, ring statement (a). It may be that more than one statement applies, in which case, please ring any that are applicable.

VISHA1	1a	I notice aches / pains less than most other people (of my age)
	b	I notice aches / pains as much as most other people (of my age)
	c	I notice aches / pains more than most other people (of my age)
	d	I am aware of aches / pains in my body all the time
VISHA2	2a	Resisting thoughts of illness is never a problem
	b	Most of the time I can resist thoughts of illness
	c	I try to resist thoughts of illness but am often unable to do so
	d	Thoughts of illness are so strong that I no longer even try to resist them
VISHA3	3a	As a rule I am not afraid that I have serious illness
	b	I am sometimes afraid that I have a serious illness
	c	I am often afraid that I have a serious illness
	d	I am always afraid that I have a serious illness
VISHA4	4a	I do not have any difficulty taking my mind off thoughts about my health
	b	I sometimes have difficulty taking my mind off thoughts about my health
	c	I often have difficulty taking my mind off thoughts about my health
	d	Nothing can take my mind off thoughts about my health
VISHA5	5a	I never think I have a serious illness
	b	I sometimes think I have a serious illness
	c	I often think I have a serious illness
	d	I usually think that I am seriously ill
VISHA6	6a	If I notice an unexplained bodily sensation I don't find it difficult to think about other things
	b	If I notice an unexplained bodily sensation I sometimes find it difficult to think about other things
	c	If I notice an unexplained bodily sensation I often find it difficult to think about other things
	d	If I notice an unexplained bodily sensation I always find it difficult to think about other things

Thank you! Please let the researcher know you have finished the questions.

You will now be asked to complete a task.

After the task, you will be asked some more questions.

For researcher's use only: ID:

Thank you for completing the task. Please complete the following questions.

1) Please put a cross on the line shown below to indicate how you feel right now.

You are being asked to rate how much you currently feel. The line is numbered and you can place a cross anywhere on the line, between numbers if you want. A mark at the extreme left end would indicate you are not feeling the sensation / emotion at all. A mark at the extreme right end would indicate that you are feeling it extremely. A mark near the centre would indicate that you feel it moderately. Please ask the researcher if this is not clear.

Not at all anxious	0 10 20 30 40 50 60 70 80 90 100	Extremely anxious
Not at all depressed	0 10 20 30 40 50 60 70 80 90 100	Extremely depressed
Not at all physically uncomfortable	0 10 20 30 40 50 60 70 80 90 100	Extremely physically uncomfortable
Not at all in pain	0 10 20 30 40 50 60 70 80 90 100	Extremely in pain
Not at all sad	0 10 20 30 40 50 60 70 80 90 100	Extremely sad
No headache at all	0 10 20 30 40 50 60 70 80 90 100	Extremely strong headache
Not at all stressed	0 10 20 30 40 50 60 70 80 90 100	Extremely stressed
No negative thoughts at all	0 10 20 30 40 50 60 70 80 90 100	Extremely strong negative thoughts
Not at all fatigued	0 10 20 30 40 50 60 70 80 90 100	Extremely fatigued
Not at all worried	0 10 20 30 40 50 60 70 80 90 100	Extremely worried

You will now be asked to complete another task.



Thank you for completing the task. Please complete the following questions.

**2) A) Please put a cross on the line shown below to indicate how you feel right now.**

You are being asked to rate how much you currently feel. The line is numbered and you can place a cross anywhere on the line, between numbers if you want. A mark at the extreme left end would indicate you are not feeling the sensation / emotion at all. A mark at the extreme right end would indicate that you are feeling it extremely. A mark near the centre would indicate that you feel it moderately. Please ask the researcher if this is not clear.

Not at all anxious	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely anxious</div> </div>
Not at all depressed	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely depressed</div> </div>
Not at all physically uncomfortable	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely physically uncomfortable</div> </div>
Not at all in pain	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely in pain</div> </div>
Not at all sad	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely sad</div> </div>
No headache at all	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely strong headache</div> </div>
Not at all stressed	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely stressed</div> </div>
No negative thoughts at all	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely strong negative thoughts</div> </div>
Not all fatigued	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely fatigued</div> </div>
Not all worried	<div style="display: flex; align-items: center;"> <div style="flex: 1; text-align: center;">           0    10    20    30    40    50    60    70    80    90    100             -----          </div> <div style="flex: 1; text-align: right;">Extremely worried</div> </div>

Please note down in the space below any ideas you had about what this experiment was looking at:

Please give your email address if you would like to receive an emailed summary of the results:



## Appendix 4: Author guidelines from Clinical Psychology Review

Available from <http://www.elsevier.com/journals/clinical-psychology-review/0272-7358/guide-for-authors>

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### Before You Begin

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#### Ethics in publishing

For information on Ethics in publishing and Ethical guidelines for journal publication see <http://www.elsevier.com/publishingethics> and <http://www.elsevier.com/journal-authors/ethics>.

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## Appendix 7: Information relating to ethical review

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07 April 2013

Dr Faith Martin  
Trainee Clinical Psychologist  
University of Bath / Taunton and Somerset NHS Trust  
Clinical Psychology Department 6 West  
University of Bath  
Claverton Down  
BA2 7AY

Dear Dr Martin

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Psychosis: Exploring Barriers, Facilitators and Potential  
Interventions  
**REC reference:** 13/LO/0508  
**IRAS project ID:** 124122

Thank you for your letter of 04 April 2013, responding to the Proportionate Review  
Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above  
research on the basis described in the application form, protocol and supporting documentation  
as revised.

We plan to publish your research summary wording for the above study on the NRES website,  
together with your contact details, unless you expressly withhold permission to do so.  
Publication will be no earlier than three months from the date of this favourable opinion letter.  
Should you wish to provide a substitute contact point, require further information, or wish to  
withhold permission to publish, please contact the Co-ordinator Mr Rajat Khullar,  
[nrescommittee.london-cityandeast@nhs.net](mailto:nrescommittee.london-cityandeast@nhs.net).

## Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.*

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

### Approved documents

The documents reviewed and approved by the Committee are:

Document	Version	Date
Covering Letter		04 April 2013
Evidence of Insurance or Indemnity		11 July 2012
Investigator CV		18 March 2013
Other: Email dated 22.03.13 explaining why this study has no issues in its participants' capacity to consent		22 March 2013
Other: Summary CV for supervisor (student research)		18 March 2013

Yours sincerely



pp Dr Arthur T. Tucker  
Chair

Email: [nrescommittee.london-cityandeast@nhs.net](mailto:nrescommittee.london-cityandeast@nhs.net)

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Lorna Hogg

## 6.2 Letter confirming Substantial amendment for Service Improvement Project



### NRES Committee London - City & East

Bristol Research Ethics Committee Centre  
Whitefriars  
Level 3, Block B  
Levens Mead  
Bristol  
BS1 2NT

Tel: 01173421386  
Fax: 01173420445

25 September 2013

Dr Faith Martin  
Trainee Clinical Psychologist  
University of Bath / Taunton and Somerset NHS Trust  
Clinical Psychology Department 6 West  
University of Bath  
Claverton Down  
BA2 7AY

Dear Dr Martin

**Study title:** Improving Client Engagement with Early Intervention for Psychosis: Exploring Barriers, Facilitators and Potential Interventions  
**REC reference:** 13/LO/0508  
**Amendment number:** AM01 Substantial Amendment A1 dated 20/08/2013  
**Amendment date:** 20 August 2013  
**IRAS project ID:** 124122

The above amendment was reviewed by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Participant Information Sheet: Participant Information Sheet	F3	19 August 2013
Protocol	F2	19 August 2013
Notice of Substantial Amendment (non-CTIMPs)	AM01 Substantial Amendment A1 dated 20/08/2013	20 August 2013
Document listing the amendments to Project 13/LO/0508	A1	19 August 2013

#### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

#### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

13/LO0508:	Please quote this number on all correspondence
------------	--

Yours sincerely



pp Dr Louise Abrams  
Vice Chair



E-mail: [nrescommittee.london-cityandeast@nhs.net](mailto:nrescommittee.london-cityandeast@nhs.net)

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Lorna Hogg*



## 6.3 Confirmation of R&D approval for Service Improvement Project

	Foundation Trust For Gloucestershire 
<b>% Gloucestershire Research &amp; Development Support Unit</b> Leadon House Gloucestershire Royal Hospital Great Western Road Gloucester GL1 3NN Telephone: 0300 4225463 Facsimile: 0300 4225469 Email: mark.walker@glos.nhs.uk	
Friday, May 10, 2013	
Dr. Faith Martin Clinical Psychologist in Training Clinical Psychology Department 6West, University of Bath Bath, BA2 7AY.	
Dear Dr. Martin,	
<b>Study Title:</b> Client Engagement with Early Intervention for Psychosis <b>REC Ref:</b> 13/L/O/0508 <b>R&amp;D Ref:</b> 13/010/2gt	
I am writing to confirm the approval of 2gether NHS Trust for the above study to commence within the Trust. Your project will now be added to the Trust Research Register which will hold full details of your study, including:	
<ul style="list-style-type: none"><li>o Title : <b>As Above</b></li><li>o Chief Investigator/Project Lead: <b>Dr. Faith Martin</b></li><li>o Sponsoring Organisation: <b>University of Bath</b></li><li>o Host Trust: <b>2gether NHS Foundation Trust</b></li></ul>	
It is important that all research conducted with NHS patients and/or staff now complies with the Research Governance Framework. In relation to this I would like to take the opportunity to remind you of some of your responsibilities under this framework.	
<ol style="list-style-type: none"><li>1. <b>Health and safety:</b> You are reminded of your responsibilities for health and safety at work under the Health and Safety at Work Act 1974. You have a legal responsibility to take care of your own and other people's Health and Safety at work under the Health and Safety at Work ACT 1974 as amended and associated legislation. These include the duty to take reasonable care to avoid injury to yourself and to others by your work activities or omissions, and to co-operate with your employer in the discharge of its statutory duties. You must adhere strictly to the policies and procedures on health and safety.</li><li>2. <b>Codes of confidentiality/Data Protection:</b> Anybody who records patient information (whether on paper or by electronic means) has a responsibility to take care to ensure that the data recorded is accurate, timely and as complete as possible. It is vital that you conduct your research in accordance with the principles of the Data Protection Act 1998.</li><li>3. <b>Liability and Indemnity:</b> The Trust accepts liability in respect of your acts and omissions to the degree that those acts and omissions were carried out whilst working on behalf of the Trust. However, the Trust expect researchers to observe the highest standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as well as acting appropriately and responsibly at all times.</li></ol>	
While undertaking officially sanctioned NHS duties, you are covered by the NHS indemnity against claims for negligence. In other circumstances (e.g. when providing services for which you receive a separate fee, or if undertaking research which has not received Trust Approval) you are not covered by the indemnity. If you intend to treat private patients on Trust premises you must have a valid indemnity. Medical practitioners are advised to maintain membership of a medical defence organisation.	
Version 5 September 2010	



4. **Intellectual Property:** Intellectual Property is defined as the tangible output of any intellectual activity that is new or previously undescribed. It can include the following:

- i. Inventions, such as new medical devices, software;
- ii. Literary works, such as software, patient leaflets, journal articles;
- iii. Designs and drawings, such as posters, leaflets;
- iv. Brand names, such as logos and trademarks; and
- v. Trade secrets, such as surgical techniques.

For projects originating from outside of the NHS Trust with which this agreement is made, Intellectual Property rights will remain with the Lead Site/Investigator unless developed from observations made outside of the scope and influence of the project. The rights to Intellectual Property generated in such a fashion will remain with the Host Trust unless an agreement to the contrary has been signed by both parties.

5. **Adverse Events/Incidents:** Any adverse events you witness or suspect to have happened must be reported to your supervisor or manager as soon as you know about them.

6. **Fraud and Misconduct:** Any suspicions of active fraud or misconduct must be reported to your supervisor or manager immediately and will be treated in the strictest confidence. The monitoring of research will also seek to reduce incidents of research misconduct and fraud.

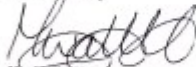
7. **Monitoring:** As part of the Research Governance Framework, during the course of your research you may be monitored to ensure that procedures in the protocol approved by the ethics committee are being adhered to.

8. **Dissemination:** The Framework also requires the dissemination of research findings to the research subjects, NHS staff and the public. On completion of your research you will be expected to produce a summary of the project and an indication of how the results from the study will be disseminated. You will receive a letter requesting this report from the Primary Care Research Governance Facilitator when you complete your research.

9. **Termination of Agreement:** The Trust also reserve the right to terminate the agreement for your research to proceed if, at any time, you are found to be in breach of the clauses in this Approval Letter or fail to adequately meet the requirements of the Research Governance Framework.

I wish you every success with your project.

Yours sincerely



Mr. Mark Walker  
Senior R&D Manager  
Gloucestershire R&D Consortium

## 6.4 Favourable opinion for NRES for Main Research Project

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.  
Yr rhan o seilwaith ymchwil Cymru a arhannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofid Cymdeithasol ac Iechyd, Llywodraeth Cymru



South East Wales Research Ethics  
Committee B  
6<sup>th</sup> Floor Churchill House  
17 Churchill Way  
Cardiff  
CF10 2TW

Telephone : 02920 376823  
E-mail : [cart.phillips@wales.nhs.uk](mailto:cart.phillips@wales.nhs.uk)  
Website : [www.nres.nhs.uk](http://www.nres.nhs.uk)

23 July 2013

Dr Faith Martin  
Trainee Clinical Psychologist  
University of Bath / Taunton and Somerset NHS Trust  
Clinical Psychology Department 6 West  
University of Bath  
Claverton Down  
BA2 7AY

Dear Dr Martin

**Study title:** The effect of mood on physical and psychological sensations in relation to alexithymia and medically unexplained symptoms  
**REC reference:** 13/WA/0213  
**IRAS project ID:** 130067

Thank you for your letter of the 22 July 2013.

I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated the 19 July 2013

### Documents received

The documents received were as follows:

Document	Version	Date
Evidence of Insurance or Indemnity	UMAL/University of Bath	15 July 2013
Evidence of Insurance or Indemnity	UMAL/University of Bath	11 July 2013

### Approved documents

The final list of approved documentation for the study is therefore as follows:

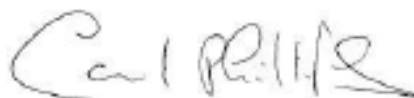
Document	Version	Date
Advertisement	F1	28 May 2013
Evidence of Insurance or Indemnity	UMAL	11 July 2012
Evidence of Insurance or Indemnity	UMAL	11 July 2012
Evidence of Insurance or Indemnity	UMAL/University of Bath	15 July 2013
Evidence of Insurance or Indemnity	UMAL/University of Bath	11 July 2013
Investigator CV	F Martin	28 May 2013
Investigator CV	P Salkovskis	28 May 2013
Letter from Sponsor	University of Bath	04 June 2013

Participant Consent Form	F1	28 May 2013
Participant Information Sheet: Recruitment Information Sheet	F1	28 May 2013
Participant Information Sheet: DeBrief Information Sheet	F1	28 May 2013
Protocol	F1	28 May 2013
Questionnaire: Validated Questionnaires	F1	28 May 2013
REC application	3.5	11 June 2013
Referees or other scientific critique report	University of Bath	17 June 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

<b>13/WA/0213</b>	<b>Please quote this number on all correspondence</b>
-------------------	---

Yours sincerely



Mr Carl Phillips  
Executive Officer  
South East Wales Research Ethics Committee B

Copied to: Dr F Martin, [psmf@bath.ac.uk](mailto:psmf@bath.ac.uk)


Professor Paul Salkovskis, [p.m.salkovskis@bath.ac.uk](mailto:p.m.salkovskis@bath.ac.uk)

Dr Jeremy Gauntlett-Gilbert, [Jeremy.Gauntlett-Gilbert@nhrd.nhs.uk](mailto:Jeremy.Gauntlett-Gilbert@nhrd.nhs.uk)

Ms J Millar, [j.l.millar@bath.ac.uk](mailto:j.l.millar@bath.ac.uk)

6.5 Front pages of R&D permissions for Main Research Project from North Bristol NHS Trust, Gloucester NHS, Avon and Wiltshire Partnership and Royal National Hospital for Rheumatic Diseases

Letter of Access 2 – 02/2013

North Bristol   
NHS Trust

Employment Services  
Ward 26, Frenchay Hospital  
Frenchay Park Road  
Bristol BS16 1LE  
Tel: 0117 3403483  
Fax: 0117 3403841  
Web: [www.nbt.nhs.uk](http://www.nbt.nhs.uk)  
Email: [pam.southgate@nbt.nhs.uk](mailto:pam.southgate@nbt.nhs.uk)

07 October 2013

Private and Confidential

Ms Faith Martin  
4001 Robinson Building  
Norfolk Place  
Bedminster  
Bristol  
BS3 4AE

Dear Ms Martin


Letter of access for research

Title of Study: 3241 – The effect of mood on physical and psychological sensations in relation to alexithymia and medically unexplained symptoms


As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through North Bristol NHS Trust for the purpose and on the terms and conditions set out below. This right of access commences on 3<sup>rd</sup> October 2013 and ends on 30<sup>th</sup> September 2014 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to North Bristol NHS Trust premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

 Peter Rilett  
Chairman

A University of Bristol Teaching Trust  
A University of the West of England Teaching Trust

 Andree Young  
Chief Executive

**Gloucestershire NHS**  
**Research & Development Support Unit**

First Floor  
Leadon House  
Gloucestershire Royal Hospital  
Great Western Road  
Gloucester  
GL1 3NN

Tel: 0300 422 5463  
Fax: 0300 422 5469  
www.glos.hospitals.nhs.uk  
Email: glos.rdsu@glos.nhs.uk

6th November 2013

Faith Martin  
Trainee Clinical Psychologist  
Clinical Psychology Department  
University of Bath and Taunton and Somerset NHS Foundation Trust  
6 West  
University of Bath  
Bath  
BA2 7AY

Dear Faith

**RE: The effect of mood on physical and psychological sensations in relation to alexithymia and medically unexplained symptoms.**

REC N°	13/WA/0213
Local R&D Ref	13/034/2GT

**Letter of access for research**

This letter should be presented to each participating organisation before you commence your research at that site. The participating organisation is 'gether NHS Foundation Trust.

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on 6th November 2103 and ends on completion of all trial-related activity, unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of assurance for research from 'gether NHS Foundation Trust.

The information supplied about your role in research at the organisation has been reviewed and you do not require an honorary research contract with the organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to the organisation.

Providing advice and support for health services research in Gloucestershire  
Hosted by Gloucestershire Hospitals NHS Foundation Trust

**Our Reference: 814AWP**

Dr Faith Martin  
Trainee Clinical Psychologist  
University of Bath / Taunton and Somerset NHS  
Trust  
Clinical Psychology Department 6 West  
University of Bath  
Claverton Down  
BA2 7AY

Hannah Antoniadou  
Research and Development  
Avon & Wiltshire Mental Health Partnership NHS Trust  
Blackberry Hill Hospital  
Blackberry Centre  
Manor Road  
Fishponds  
Bristol  
BS16 2EW  
0117 378 4267

Date: 08 October 2013

[hannah.antoniadou@awp.nhs.uk](mailto:hannah.antoniadou@awp.nhs.uk)

Dear Dr Martin,

**Title of study:** The effect of mood on physical and psychological sensations in relation to alexithymia and medically unexplained symptoms  
**Approval date:** 08 October 2013  
**End date:** 31 August 2013

Thank you very much for applying to undertake your research in AWP, we pride ourselves on a straight forward and rapid process for research governance and project management.

We are pleased to advise that we have been able to grant R&D Permission at Avon and Wiltshire Mental Health Partnership NHS Trust ("the Trust").

We hope that you are successful in your recruitment aims and objectives. Please make sure that you let us know at the end of your study how it went by providing us with a copy of your final report. This way we can ensure those involved within the Trust are aware of your findings and can consider your recommendations. Please send a copy of your final report to [research@awp.nhs.uk](mailto:research@awp.nhs.uk).

The R&D Permission in the Trust is valid until **31 August 2013**. If you require any extension to this in the future please contact us to arrange.

The documentation listed below has been received and all the relevant governance checks have now been completed.

I am therefore happy to provide R&D Permission for the above study across all locations within the Trust parameters.

Document	Version	Date
Evidence of Insurance or indemnity	UMAL/University of Bath	15 July 2013
Advertisement	F1	28 May 2013
Evidence of Insurance or indemnity	UMAL	11 July 2012
Evidence of Insurance or indemnity	UMAL	11 July 2012
Evidence of Insurance or indemnity	UMAL/University of Bath	15 July 2013
Evidence of Insurance or indemnity	UMAL/University of Bath	11 July 2013

Continued...

Chair  
Anthony Gallagher

Headquarters  
Jenner House, Langley Park, Chippenham. SN15 1GG

Chief Executive  
Iain Tuley



# Royal National Hospital for Rheumatic Diseases

NHS Foundation Trust

Faith Martin  
Trainee Clinical Psychologist  
Clinical Psychology  
6 West, University of Bath  
Claverton Down  
Bath BA2 7AY

Upper Borough Walls  
Bath, BA1 1RL

Telephone: 01225 465941  
Facsimile: 01225 421202

8<sup>th</sup> August 2013

Dear Faith

## Letter of access for research

This letter confirms your right of access to conduct research through the Royal National Hospital for Rheumatic Diseases (RNHRD) for the purpose and on the terms and conditions set out below. This right of access commences on the 8<sup>th</sup> August 2013 and ends on 29<sup>th</sup> August 2014 unless terminated earlier in accordance with the clauses below.

The information supplied about your role in research at RNHRD has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out as detailed by Musgrove Park Hospital. You are considered to be a legal visitor to RNHRD premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through the RNHRD, you will remain accountable to Musgrove Park Hospital but you are required to follow the reasonable instructions of Dr Jeremy Gauntlett-Gilbert in this NHS organisation or those given on her behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with the RNHRD policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with RNHRD in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on RNHRD premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and

